IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF OHIO
EASTERN DIVISION

IN RE NATIONAL PRESCRIPTION OPIATE LITIGATION

This document relates to:
Case No. 1:_-op-__-DAP

CITY OF SARASOTA,

Plaintiff,

vs.

WALGREEN CO.; WALGREENS BOOTS ALLIANCE, INC.; PUBLIX SUPER MARKETS, INC.; WALMART INC., F/K/A WAL-MART STORES, INC.; WAL-MART STORES EAST, LP; WAL-MART STORES EAST, LLC F/K/A WAL-MART STORES EAST INC.; WSE MANAGEMENT, LLC; WSE INVESTMENT LLC; SAM'S EAST, INC.; AND SAM'S WEST, INC.,

Defendants.

MDL No. 2804

Case No. 17-md-2804

Judge Dan Aaron Polster

COMPLAINT/

DEMAND FOR JURY TRIAL

TABLE OF CONTENTS

Page

TABLE OF CONTENTS

Page

TABLE OF CONTENTS

Page

1. Plaintiff City of Sarasota, Florida ("Sarasota," the "City" or "Plaintiff") brings this action to prevent future harm and to redress past wrongs against the following Defendants ("Defendants," "Chain Pharmacies," or "Pharmacy Defendants"): the Walgreens Defendants,[1] Publix Super Markets, Inc. ("Publix"), and the Walmart Defendants.[2]

2. Plaintiff seeks to hold accountable the Chain Pharmacies that reaped enormous financial rewards by refusing to monitor and restrict the improper sale and distribution of opioids and abate the opioid epidemic in the City.

INTRODUCTION

3. This case arises from the worst man-made epidemic in modern medical history—an epidemic of addiction, overdose and death caused by Defendants' flooding the United States, including Plaintiff's community, with prescription opioids.

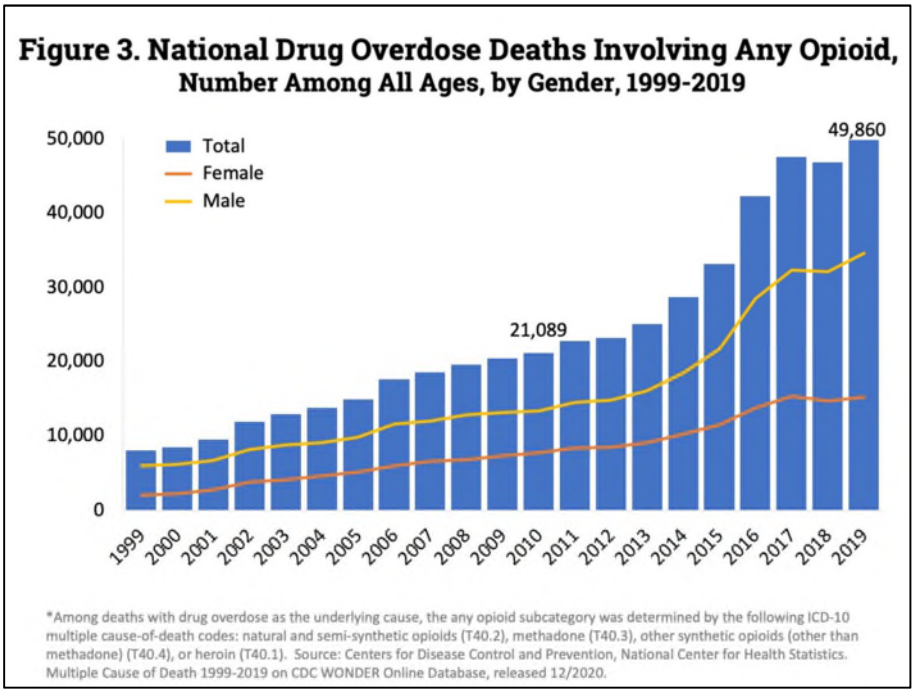
4. By now, most Americans have been affected, either directly or indirectly, by the opioid epidemic. This crisis arose not only from the opioid manufacturers' deliberate marketing strategy, but from distributors' and pharmacies' equally deliberate efforts to evade restrictions on opioid distribution and dispensing, while also helping spread the manufacturers' false marketing messages about prescription opioids and encourage their widespread use. These distributors and pharmacies acted without regard for the lives that would be trammeled in pursuit of profit.

5. Since the push to expand prescription opioid use began in the late 1990s, the death toll has climbed, with no sign of slowing. The number of opioid overdoses in the United States rose from 8,000 in 1999 to over 20,000 in 2009, and over 33,000 in 2015. In the twelve months

[1] The Walgreens Defendants are Walgreen Co. and Walgreens Boots Alliance, Inc.

[2] The Walmart Defendants are Walmart Inc., f/k/a Wal-Mart Stores, Inc.; Wal-Mart Stores East, LP; Wal-Mart Stores East, LLC f/k/a Wal-Mart Stores East Inc.; WSE Management, LLC; WSE Investment LLC; Sam's East, Inc.; and Sam's West, Inc.

that ended in September 2017, opioid overdoses claimed 45,000 lives. Another 46,000 opioid overdose deaths occurred in 2018, and in 2019 the number of opioid overdose deaths rose to over 49,000.



6. Preliminary data indicates that the number of opioid related overdose deaths will be in excess of 65,000 for 2020. In Florida, "opioid-related deaths increased by 28%, with 7,842 deaths reported" in 2020, according to the state's medical examiners.[3] "More directly, 6,089 Floridians died directly due to opioids, a 42% increase compared to 2019."[4]

7. From 1999 through 2016, more than 350,000 people died from an overdose involving any opioids. Well over half of those deaths—over 200,000 people—involved opioids prescribed by doctors to treat pain. These opioids include brand-name prescription medications like OxyContin, Opana ER, Vicodin, Subsys, and Duragesic, as well as generics like oxycodone, hydrocodone, and fentanyl.

---

[3] Sam Sachs, *Florida Opioid Deaths Up 42% During 1st Year of COVID-19 Pandemic*, Florida opioid deaths up 42% during 1st year of COVID-19 pandemic | WFLA

[4] *Id.*

8. Most of the overdoses from non-prescription opioids are also directly related to prescription pills. As soon as prescription opioids took hold on a population, the logical and devastating progression to illicit drugs followed. Many opioid users, having become addicted to but no longer able to obtain prescription opioids or trapped in a cycle of addiction that causes those who suffer from the disease to need stronger and more potent drugs, have turned to heroin, fentanyl, and other illicit drugs. According to the American Society of Addiction Medicine, 80% of people who initiated heroin use in the past decade started with prescription painkillers—which, at the molecular level and in their effect, closely resemble heroin. In fact, people who are addicted to prescription painkillers are 40 times more likely to become addicted to heroin, and the CDC identified addiction to prescription pain medication as the strongest risk factor for heroin addiction.

9. The conduct of the manufacturers, distributors, and Chain Pharmacies caused the nation, and the City, to be awash in a flood of prescription opioids. This has had a profound impact on both morbidity and mortality, and these drugs have created an epidemic of addiction that has had severe and wide-ranging effects on public health and safety in the City and in communities across the country. Indeed, from those suffering with the disease of addiction themselves, to children whose parents who suffer from addiction, to employers who employ an addicted population, to the first responders, law enforcement, the court system and the prison system, there is almost no area of the community that has not been significantly impacted.

10. As a result, in part, of the proliferation of opioid pharmaceuticals between the late 1990s and 2015, the life expectancy for Americans decreased for the first time in recorded history. Drug overdoses are now the leading cause of death for Americans under 50.

11. In the words of Robert Anderson, who oversees death statistics at the Centers for Disease Control and Prevention, “I don’t think we’ve ever seen anything like this. Certainly not

in modern times." On October 27, 2017, the President declared the opioid epidemic a public health emergency.

12. Florida is suffering the effects of this unprecedented addiction epidemic. Of the 33,000 people who died nationwide of opioid overdoses in 2015, approximately 12% were Floridian. On May 4, 2017, Governor Risk Scott officially declared the opioid epidemic a public health emergency in Florida, stating, "The individuals struggling with drug use are sons, daughters, mothers, fathers, sisters, brothers, and friends, and each tragic case leaves loved ones searching for answers and praying for help. Families across our nation are fighting the opioid epidemic, and Florida is going to do everything possible to help our communities."[5]

13. The loss of each of these individuals cannot be adequately conveyed by statistics, nor can the depth and breadth of the impact on those who survive. Because the addictive pull of opioids is so strong, relapse is more common than with other drugs. Further, overdose deaths are not the only consequence.

14. The region made up of Sarasota, Manatee and DeSoto counties has been hit hard by the opioid epidemic. The area has seen opioid usage and accidental overdose deaths rise to alarming levels — from 246 drug overdose deaths in 2015 to 263 in 2016.[6] At least thirty-nine of those in 2016 were related to prescription opioid usage.[7] By July 2017 Sarasota County detectives had already

[5] Michael Auslen, *Gov. Scott declares public health emergency over opioid crisis*, Miami Herald (May 3, 2017), available at http://www.miamiherald.cominews/health-care/article148355444.html.

[6] Zac Anderson, *Overdose Deaths keep climbing in Southwest Florida*, Sarasota Herald-Tribune (July 27, 2017), available at https://www.heraldtribune.com/story/news/local/manatee/2017/07/27/overdose-deaths-keep-climbing-in-southwest-florida/20065348007/

[7] Zac Anderson, *Governor puts spotlight on opioid problem during Sarasota visit*, Daytona Beach News-Journal (July 11, 2017), available at https://www.heraldtribune.com/story/news/local/sarasota/2017/07/11/governor-puts-spotlight-on-opioid-problem-during-sarasota-visit/20281348007/

responded to 185 opioid-related overdoses and investigated 32 opioid-related deaths. Moreover, Sarasota and Manatee Counties were the top two communities in Florida for fentanyl-caused deaths in 2015.

15. As such, the City sits squarely in the crosshairs of the opioid-fueled-epidemic. Upon information and belief, Sarasota spends millions of dollars each year to provide a wide range of opioid-and-addiction-related services for its residences and visitors — money that it would not have had to spend but for the extreme and continuing public nuisance caused by Defendants' actions — including, as just one example, law enforcement and emergency response services and treatment.

16. In fact, the City has seen an unprecedented growth in the drug addiction treatment industry, which now helps people from across the country who are desperately seeking treatment for an opioid addiction that was caused by defendants' failure to report suspicious orders of opioid medication.

17. This devastation in the City was created by opioid manufacturers, distributors, and Chain Pharmacies, who worked together to systematically dismantle the narcotic conservatism that had existed around prescription opioids for decades, opened the floodgates to an unreasonably large and unsafe supply of opioids, improperly normalized the widespread use of opioid drugs, violated laws and regulations designed to protect the public from the dangers of narcotic drugs like opioids, and worked to dismantle protections designed to protect the public so more opioid drugs could be sold and the manufacturers, distributors, and Chain Pharmacies could reap the profits therefrom.

18. This suit takes aim at a substantial contributing cause of the opioid crisis: the Chain Pharmacies, the last link in the opioid supply chain and the critical gatekeeper between dangerous

opioid narcotics and the public, who utterly failed in their gatekeeper role, flouted their duties to protect the public, violated the laws designed to protect the public and dismantled and disregarded measures designed to protect the public health and safety. The Chain Pharmacies failed to design and operate systems to identify suspicious orders of prescription opioids, maintain effective controls against diversion, and halt suspicious orders when they were identified, and instead actively contributed to the oversupply of such drugs and fueled an illegal secondary market. They also played an active role in helping the manufacturers promote their false marketing about opioids to health care providers, their own pharmacists, and the public.

19. The mission of pharmacy practice is "to serve society as the profession responsible for the appropriate use of medications, devices, and services to achieve optimal therapeutic outcomes."[8] Defendants subverted that role and instead played a significant role in a public health epidemic in the City.

20. Defendants have contributed substantially to the opioid crisis by helping to inflate the opioid market beyond any legitimate bounds and by flooding that market with far greater quantities of prescription opioids than they know could be necessary for legitimate medical uses, while failing to report, and to take steps to halt suspicious orders and sales, thereby exacerbating the oversupply of such drugs and fueling an illegal secondary market.

21. In 2014, almost two million Americas were addicted to prescription opioids and another 600,000 to heroin. From 1999 to 2015, more than 183,000 people died in the U.S. from overdoses related to prescription opioids—more than the number of Americans who died in the Vietnam War. From 1999 to 2016, more than 200,000 people died in the U.S. from overdoses

[8] Vision and Mission for the Pharmacy Profession, American Pharmacists Association, adopted by the APhA House of Delegates (March 1991).

related to prescription opioids. Overdose deaths involving prescription opioids were five times higher in 2017 than 1999. The number of drug overdose deaths increased by nearly 5% from 2018 to 2019.

22. As millions became addicted to opioids, "pill mills," often styled as "pain clinics," sprouted nationwide and rogue prescribers stepped in to supply prescriptions for non-medical use. These pill mills, typically under the auspices of licensed medical professionals, issue high volumes of opioid prescriptions under the guise of medical treatment. Prescription opioid pill mills and rogue prescribers cannot channel opioids for illicit use without at least the tacit support and willful blindness of the Defendants, if not their knowing support.

23. As a direct and foreseeable result of Defendants' conduct, cities and counties across the nation, including Plaintiff, are now swept up in what the Centers for Disease Control ("CDC") has called a "public health epidemic" and what the U.S. Surgeon General has deemed an "urgent health crisis."[9] The increased volume of opioid prescribing, not all of which is for legitimate use, correlates directly to skyrocketing addiction, overdose and death; black markets for diverted prescriptions opioids; and a concomitant rise in heroin and fentanyl abuse by individuals who could no longer legally acquire or could not afford prescription opioids.

24. This explosion in opioid use and Defendants' profits has come at the expense of patients and residents and has caused ongoing harm to and a public nuisance in the City. As the then CDC director concluded: "We know of no other medication routinely used for a nonfatal condition that kills patients so frequently."[10]

---

[9] *Examining the Growing Problems of Prescription Drug and Heroin Abuse*, Ctrs. For Disease Control and Prevention (Apr. 29, 2014), http://www,cdc,give.washington/testimony/2014/t20140429.htm; *see also*, Letter from Vivek H. Murthy, Surgeon General, Tide RX (Aug. 2016), http://turnthetiderx.org.

[10] *Id.*

25. Defendants' conduct in promoting opioid use and fueling diversion has had severe and far-reaching public health, social services, and criminal justice consequences, including the fueling of addiction and overdose from illicit drugs such as heroin. The costs are borne by Plaintiff and other governmental entities.

26. The burdens imposed on Plaintiff are not the normal or typical burdens of government programs and services. Rather, these are extraordinary costs and losses that are related directly to Defendants' illegal actions. The Defendants' conduct has created a public nuisance and a blight. Governmental entities, and the services they provide their citizens, have been strained to the breaking point by this public health crisis.

27. Defendants have not changed their ways or corrected their past misconduct but instead are continuing to fuel the crisis and perpetuate the public nuisance.

28. Within the next hour, six Americans will die from opioid overdoses; two babies will be born dependent on opioids and begin to go through withdrawal.

29. Plaintiff brings this suit to bring the devastating march of this epidemic to a halt and to hold Defendants responsible for the crisis they caused.

JURISDICTION AND VENUE

30. This Court has subject-matter jurisdiction of this action pursuant to 28 U.S.C. § 1331 because the City's claim under the Racketeer Influenced and Corrupt Organizations Act ("RICO"), 18 U.S.C. § 1961 *et seq.* raises a federal question. This Court has supplemental and pendent jurisdiction over the City's state-law claims under 28 U.S.C. § 1367 because those claims are so related to the RICO claim as to form part of the same case or controversy.

31. This court has personal jurisdiction over Defendants pursuant to Fla. Stat. Ann. § 48.193 because they transact business in the state of Florida, contract to supply goods and manufactured products in the state of Florida, carry on a continuous and systematic part of their

general businesses within Florida, including in Sarasota, have transacted substantial business with Florida and Sarasota entities and residents, and have caused grave harm in the City as a result.

32. Venue is proper in this court pursuant to 28 U.S.C. § 1391(b)(2) because a substantial part of the events and omissions giving rise to the claim occurred in the United States District Court for the Middle District of Florida. Venue is also proper under 18 U.S.C. § 1965(a) because Defendants reside, are found, have agents, or transact their affairs in the Middle District of Florida, and this case is subject to transfer to *In re National Prescription Opiate Litigation MDL*, 1:17-md-02804 (N.D. Ohio) ("MDL 2804"). Under Case Management Order One, *In re National Prescription Opiate Litigation MDL*, 1:17-md-02804, Rec. Doc. 232 (N.D. Ohio), "to eliminate delays associated with transfer to this Court of cases filed in or removed to other federal district courts, any Plaintiff whose case would be subject to transfer to these MDL proceedings may file its case directly in this District." *Id.* ¶ 6.a.

PARTIES

I. PLAINTIFF

33. The City of Sarasota is a municipal corporation organized under the laws of the State of Florida. Sarasota is responsible for the public health, safety, and welfare of its residents, is a citizen of the State of Florida for diversity purposes and has the capacity to sue and be sued. The City has been authorized by the Commission to bring this suit.

II. DEFENDANTS

A. Walgreens

34. Defendant Walgreen Co. acted as a retail pharmacy in the United States, until Walgreen Co. completed the acquisition of Alliance Boots, a British pharmacy giant, in 2014. After this acquisition, the company simply became Walgreens Boots Alliance, Inc. traded on NASDAQ under the symbol WBA.

35. Defendant Walgreens Boots Alliance, Inc. is a Delaware corporation that describes itself as the successor of Walgreen Co., an Illinois corporation. Both Walgreens Boots Alliance, Inc. and Walgreen Co. have their principal place of business in Illinois.

36. Walgreen Co. is portrayed as a subsidiary of Walgreens Boots Alliance, Inc. and does business under the trade name "Walgreens."

37. During the relevant time period, Walgreens self-distributed opioids and cocktail drugs to its own pharmacies from distribution centers which it owned and operated. At least between 2006 and 2014, Walgreens distributed opioids and cocktail drugs from its distribution centers, including, upon information and belief, its Jupiter, Florida distribution center, to Walgreens retail pharmacies located in Florida, including the City.

38. Defendants Walgreens Boots Alliance, Inc. and Walgreen Co. are collectively referred to as "Walgreens."

39. Walgreens conducted business as a licensed wholesale distributor, as described above. Throughout the relevant time period, and as further alleged below, Walgreens entities also owned and operated pharmacies in the City. At all times relevant to this Complaint, Walgreens distributed and/or sold prescription opioids throughout the United States, including in Florida.

40. Upon information and belief, the DEA distribution registrations for Walgreens's controlled substances distribution centers that distributed opioids and cocktail drugs into the City were held by Walgreen Co.

41. Walgreen Co. created, implemented, and had the power to enforce policies, practices, and training regarding distribution and sales in all Walgreens distribution and pharmacy sales operations.

42. Upon information and belief, the DEA dispensing registrations for Walgreens's pharmacies in the City were held by Walgreen Co., which operated each pharmacy as a "d/b/a/" entity.

B. Publix

43. Defendant Publix Super Markets, Inc. ("Publix") is a Florida corporation with its principal place of business in Lakeland, Florida.

44. Publix, through its various DEA registrant subsidiaries and affiliated entities, conducts business as a registered wholesale distributor and as a pharmacy.

45. Publix operates approximately 1,264 supermarkets across Florida, Georgia, Alabama, North and South Carolina, Tennessee, including stores located in the City.

46. As of 2014, Publix operated 929 pharmacies in the southeastern United States, with sales exceeding $2.2 billion annually.

47. At all times relevant to this Complaint, Publix distributed and sold prescription opioids through the southeastern United States, including in Florida and the City specifically.

C. Walmart

48. Defendant Walmart Inc., formerly known as Wal-Mart Stores, Inc., is a Delaware corporation with its principal place of business in Bentonville, Arkansas.

49. Defendant Wal-Mart Stores East, LP is a Delaware limited partnership with its principal place of business in Arkansas.

50. Defendant Wal-Mart Stores East, LLC f/k/a Wal-Mart Stores East Inc. is an Arkansas limited liability company with its principal place of business in Bentonville, Arkansas.

51. Defendant Sam's East, Inc., d/b/a Sam's Club, is an Arkansas corporation with its principal place of business in Arkansas. Sam's East, Inc. is an indirectly, wholly owned subsidiary of Walmart Inc. The sole shareholder of Sam's East, Inc. is Defendant Sam's West, Inc. d/b/a

Sam's Club, which is a wholly owned direct subsidiary of Walmart Inc. and an Arkansas corporation. Defendants Sam's East, Inc. and Sam's West, Inc. jointly operate Sam's Club stores.

52. Walmart Inc. is the sole owner of Sam's West, Inc. Sam's West, Inc. is the sole shareholder of Sam's East, Inc.

53. Defendant WSE Management, LLC, is a Delaware limited liability company, and owns one percent of Wal-Mart Stores East, LP.

54. Defendant WSE Investment, LLC, is a Delaware limited liability company, and a ninety-nine percent owner of Wal-Mart Stores East, LP.

55. The sole owner and member of both WSE Management, LLC and WSE Investment, LLC is Wal-Mart Stores East LLC (formerly known as Wal-Mart Stores East, Inc.), an Arkansas limited liability company.

56. The sole shareholder of Wal-Mart Stores East, Inc. is Walmart Inc., f/k/a Wal-Mart Stores, Inc.

57. Defendants Walmart Inc., f/k/a Wal-Mart Stores, Inc., Wal-Mart Stores East, LP, Wal-Mart Stores East, LLC f/k/a Wal-Mart Stores East Inc., WSE Management, LLC, WSE Investment LLC, Wal-Mart Stores East, Inc., Sam's East, Inc., and Sam's West, Inc., are collectively referred to as "Walmart."

58. Walmart, through its various DEA registrant subsidiaries and affiliated entities, conducts business as a registered wholesale distributor and as a pharmacy.

59. At all times relevant to this Complaint, Walmart distributed and/or sold prescription opioids throughout the United States, including in Florida and the City specifically.

D. Related Entities; Agency and Authority

60. Defendants include the entities named above as well as their predecessors, successors, affiliates, subsidiaries, partnerships and divisions to the extent that they are engaged in the manufacture, promotion, distribution, sale, and/or dispensing of opioids.

61. All of the actions described in this Complaint are part of, and in furtherance of, the unlawful conduct alleged herein, and were authorized, ordered, and/or done by Defendants' officers, agents, employees, or other representatives while actively engaged in the management of Defendants' affairs within the course and scope of their duties and employment, and/or with Defendants' actual, apparent, and/or ostensible authority.

62. Plaintiff alleges that the corporate parents named as Defendants in this Complaint are liable as a result of their own actions and obligations in distributing and selling opioids, and not solely because of their vicarious responsibility for the actions of their pharmacy stores.

DEFENDANTS' CONDUCT AND PLAINTIFF'S INJURIES

I. COMMON FACTS[11]

A. Opioids and Their Effects

63. The term "opioid" refers to a class of drugs that bind with opioid receptors in the brain and includes natural, synthetic, and semi-synthetic opioids. Natural opioids are derived from the opium poppy. Generally used to treat pain, opioids produce multiple effects on the human body, the most significant of which are analgesia, euphoria, and respiratory depression.

64. The medicinal properties of opioids have been recognized for millennia—as well as their potential for abuse and addiction. The opium poppy contains various opium alkaloids, three of which are used in the pharmaceutical industry today: morphine, codeine, and thebaine.

[11] The allegations in this Complaint are made upon information and belief, including upon information immediately available to Plaintiff from public ARCOS information.

Early use of opium in Western medicine was with a tincture of opium and alcohol called laudanum, which contains all of the opium alkaloids and is still available by prescription today. Chemists first isolated the morphine and codeine alkaloids in the early 1800s.

65. In 1827, the pharmaceutical company Merck began large-scale production and commercial marketing of morphine. During the American Civil War, field medics commonly used morphine, laudanum, and opium pills to treat the wounded, and many veterans were left with morphine addictions. By 1900, an estimated 300,000 people were addicted to opioids in the United States, and many doctors prescribed opioids solely to prevent their patients from suffering withdrawal symptoms. The nation's first Opium Commissioner, Hamilton Wright, remarked in 1911, "The habit has this nation in its grip to an astonishing extent. Our prisons and our hospitals are full of victims of it, it has robbed ten thousand businessmen of moral sense and made them beasts who prey upon their fellows . . . it has become one of the most fertile causes of unhappiness and sin in the United States."[12]

66. In 1898, Bayer Pharmaceutical Company began marketing diacetylmorphine (obtained from acetylation of morphine) under the trade name "Heroin." Bayer advertised heroin as a non-addictive cough and cold remedy suitable for children, but as its addictive nature became clear, heroin distribution in the U.S. was limited to prescription only in 1914 and then banned altogether a decade later.

67. Although heroin and opium became classified as illicit drugs, there is little difference between them and prescription opioids. Prescription opioids are synthesized from the

[12] Nick Miroff, *From Teddy Roosevelt to Trump: How Drug Companies Triggered an Opioid Crisis a Century Ago*, The Wash. Post (Oct. 17, 2017), https://www.washingtonpost.com/news/retropolis/wp/2017/09/29/the-greatest-drug-fiends-in-the-world-an-american-opioid-crisis-in-1908/?utm_term=.7832633fd7ca.

same plant as heroin, have similar molecular structures, and bind to the same receptors in the human brain.

68. Due to concerns about their addictive properties, prescription opioids have usually been regulated at the federal level as Schedule II controlled substances by the DEA since 1970.

69. Medical professionals describe the strength of various opioids in terms of morphine milligram equivalents ("MME"). According to the CDC, doses at or above 50 MME/day double the risk of overdose compared to 20 MME/day, and one study found that patients who died of opioid overdose were prescribed an average of 98 MME/day.

70. Patients develop tolerance to the analgesic effect of opioids relatively quickly. As tolerance increases, a patient typically requires progressively higher doses in order to obtain the same perceived level of pain reduction. The same is true of the euphoric effects of opioids—the "high." However, opioids depress respiration, and at very high doses can and often do arrest respiration altogether. At higher doses, the effects of withdrawal are more severe. Long-term opioid use can also cause hyperalgesia, a heightened sensitivity to pain.

71. Discontinuing opioids after more than just a few weeks will cause most patients to experience withdrawal symptoms. These withdrawal symptoms include: severe anxiety, nausea, vomiting, headaches, agitation, insomnia, tremors, hallucinations, delirium, pain, and other serious symptoms, which may persist for months after a complete withdrawal from opioids, depending on how long the opioids were used.

B. Defendants' Conduct Created an Abatable Public Nuisance

72. As alleged throughout this Complaint, Defendants' conduct has created a public health crisis and a public nuisance.

73. The public nuisance created, perpetuated, and maintained by Defendants can be abated and further recurrence of such harm and inconvenience can be abated by taking measures

such as providing addiction treatment to patients who are already addicted to opioids, making naloxone widely available so that overdoses are less frequently fatal, and a number of other proven measures to address the epidemic.

74. Defendants have the ability to act to help end the public nuisance, and the law recognizes that they are uniquely well positioned to do so. All companies in the supply chain of a controlled substance are primarily responsible for ensuring that such drugs are only distributed and sold to appropriate patients and not diverted. These responsibilities exist independent of any Food and Drug Administration ("FDA") or Drug Enforcement Administration ("DEA") regulation, to ensure that their products and practices meet both federal and state laws and regulations. As registered distributors and dispensers of controlled substances, Defendants are placed in a position of special trust and responsibility and are uniquely positioned, based on their knowledge of prescribers and orders, to act as a key line of defense. Defendants, however, instead abused their position of special trust and responsibility within the closed system of opioid distribution and dispensing and fostered a black market for prescription opioids.

C. Defendants Deliberately Disregarded Their Duties to Maintain Effective Controls Against Diversion.

1. The Chain Pharmacies Were on Notice of and Contributed to Illegal Diversion of Prescription Opioids.

75. Retail pharmacy chains earned enormous profits by flooding the country with prescription opioids. They were keenly aware of the oversupply of prescription opioids through the extensive data and information they developed and maintained as both distributors and retail sellers of opioids. Yet, instead of taking any meaningful action to stem the flow of opioids into communities, they continued to participate in the oversupply and profit from it.

76. Each of the Chain Pharmacies does substantial business in Florida. Publix does so throughout the Southeast and Walgreens and Walmart throughout the United States. This business includes the distribution and sale of prescription opioids.

77. Statewide and county-level ARCOS data confirms that the Chain Pharmacies distributed and dispensed substantial quantities of prescription opioids in the City. In addition, they distributed and dispensed substantial quantities of prescription opioids in other parts of Florida, and upon information and belief, these drugs were diverted from other parts of Sarasota County or Florida to the City. The Chain Pharmacies failed to take meaningful action to stop this diversion despite their knowledge of it, and thus contributed substantially to the diversion problem.

78. The Chain Pharmacies developed and maintained extensive data on the opioids they distributed and dispensed. Through this data, Chain Pharmacies had direct knowledge of patterns and instances of improper distribution, prescribing, sale, and use of prescription opioids in communities throughout the country, and in the City in particular. They used the data to evaluate their own sales activities and workforce. The Chain Pharmacies also provided data regarding, *inter alia*, individual doctors to drug companies, which targeted those prescribers with their marketing, in exchange for rebates or other forms of consideration. The Chain Pharmacies' data is a valuable resource that they could and should have used to help prevent diversion, but they failed to do so. Defendants facilitated the supply of far more opioids that could have been justified to serve a legitimate market. The failure of the Defendants to maintain effective controls, and to investigate, report, and take steps to halt orders that they knew or should have known were suspicious, as well as to maintain effective policies and procedures to guard against diversion from their retail stores, breached both their statutory and common law duties.

79. For over a decade, Defendants aggressively sought to bolster their revenue, increase profit, and grow their share of the prescription painkiller market by unlawfully and surreptitiously increasing the volume of opioids they sold. However, Defendants are not permitted to engage in a limitless expansion of their sales through the unlawful sales of regulated painkillers.

80. Each participant in the supply chain of opioid distribution, including the Chain Pharmacies, is responsible for preventing diversion of prescription opioids into the illegal market by, among other things, monitoring, and reporting suspicious activity.

81. According to the CDC, opioid prescriptions, as measured by number of prescriptions and morphine milligram equivalent ("MME") per person, tripled from 1999 to 2015. In 2015, on an average day, more than 650,000 opioid prescriptions were dispensed in the U.S. Not all of these prescriptions were legitimate. Yet Defendants systemically ignored red flags that they were fueling a black market, and failed to maintain effective controls against diversion at both the wholesale and retail pharmacy level. Instead, they put profits over the public health and safety. Despite their legal obligations as registrants under the CSA, the Chain Pharmacies allowed widespread diversion to occur—and they did so knowingly.

82. Upon information and belief, this problem was compounded by the Chain Pharmacies' failure to adequately train their pharmacists and pharmacy technicians on how to properly and adequately handle prescriptions for opioid painkillers, including what constitutes a proper inquiry into whether a prescription is legitimate and what measures and/or actions to take when a prescription is identified as potentially illegitimate.

83. Upon information and belief, the Chain Pharmacies also failed to put in place effective policies and procedures to prevent their stores from facilitating diversion and selling into a black market, and to conduct adequate internal or external reviews of their opioid sales to identify

patterns regarding prescriptions that should not have been filled, or if they conducted such reviews, they failed to take any meaningful action as a result.

84. Upon information and belief, even where Chain Pharmacies enacted policies and procedures to prevent stores from facilitating diversion and selling into a black market, such policies were merely window-dressing and were not employed in any meaningful way.

85. Upon information and belief, the Chain Pharmacies also failed to effectively respond to concerns raised by their own employees regarding inadequate policies and procedures regarding the filling of opioid prescriptions. Instead, Chain Pharmacies put in place policies that required and rewarded speed and volume over safety and the care necessary to ensure that narcotics were distributed and sold lawfully. Defendants consistently put profits over safety in their distribution and sale of prescription opioids.

86. The Chain Pharmacies were, or should have been, fully aware that the quantity of opioids being distributed and dispensed by them was untenable, and in many areas patently absurd. But they did not take meaningful action to investigate or to ensure that they were complying with their duties and obligations under the law with regard to controlled substances.

2. Defendants Have a Duty to Report Suspicious Orders and Not to Ship Those Orders Unless Due Diligence Disproves Their Suspicions

87. Multiple sources impose duties on the Defendants to report suspicious orders and further not to ship those orders unless due diligence disproves those suspicions.

88. First, under the common law, Defendants had a duty to exercise reasonable care in delivering dangerous narcotic substances. By flooding Florida, and the City, with more opioids than could be used for legitimate medical purposes, by filling and failing to report orders that they knew or should have realized were likely being diverted for illicit uses, and by failing to maintain

effective controls against diversion from their retail stores, Defendants breached that duty and both created and failed to prevent a foreseeable risk of harm.

89. Second, each of the Defendants assumed a duty, when speaking publicly about opioids and their efforts to combat diversion, to speak accurately and truthfully.

90. Third, distributors and chain pharmacies are required to register with the DEA to distribute and/or dispense controlled substances under the federal Controlled Substances Act. *See* 21 U.S.C. § 823(a)-(b), (e); 28 C.F.R. § 0.100; 28 C.F.R. § 1301.71. Recognizing a need for greater scrutiny over controlled substances due to their potential for abuse and danger to public health and safety, the United States Congress enacted the Controlled Substances Act in 1970. The CSA and its implementing regulations created a closed-system of distribution for all controlled substances and listed chemicals. Congress specifically designed the closed chain of distribution to prevent the diversion of controlled substances into the illicit market. Congress was concerned with the diversion of drugs out of legitimate channels of distribution and acted to halt the "widespread diversion of [controlled substances] out of legitimate channels into the illegal market." Moreover, the closed-system was specifically designed to ensure that there are multiple ways of identifying and preventing diversion through active participation by registrants within the drug delivery chain. All registrants must adhere to the specific security, recordkeeping, monitoring and reporting requirements that are designed to identify or prevent diversion. Maintaining the closed system under the CSA and effective controls to guard against diversion is a vital public health concern. Controlled substances, and prescription opioids specifically, are recognized as posing a high degree of risk from abuse and diversion. When the supply chain participants at any level fail to fulfill their obligations, the necessary checks and balances collapse. The result is the scourge of addiction that has occurred.

91. As registrants, Defendants were required to "maint[ain] . . . effective controls against diversion" and to "design and operate a system to disclose . . . suspicious orders of controlled substances." 21 U.S.C. § 823(a)-(b); 21 C.F.R. § 1301.74. Defendants were further required to take steps to halt suspicious orders. Defendants violated their obligations under federal law. Defendants have additional duties under Florida's controlled substances laws and common law. *See* Florida Comprehensive Drug Abuse Prevention and Control Act, Fla. Stat. Ann. § 893.031.

92. Further, under the CSA, pharmacy registrants are required to "provide effective controls and procedures to guard against theft and diversion of controlled substances." *See* 21 C.F.R. § 1301.71(a). In addition, 21 C.F.R. § 1306.04(a) states, "[t]he responsibility for the proper prescribing and dispensing of controlled substances is upon the prescribing practitioner, but a corresponding responsibility rests with the pharmacist who fills the prescription." Thus, regardless of whether they are registrants, all dispensers must ensure that prescriptions of controlled substances are "issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice." 21 C.F.R. § 1306.04(a). The DEA has recognized that "as dispensers of controlled substances, pharmacists and pharmacy employees are often the last line of defense in preventing diversion."[13]

93. "A prescription for a controlled substance may only be filled by a pharmacist, acting in the usual course of his professional practice." 21 C.F.R. § 1306.06. As the Department of Justice's recent lawsuit against Walmart alleges, 21 C.F.R. § 1306.06 requires that a pharmacist's conduct, when filling controlled-substance prescriptions adhere to the usual course

[13] 2012 Dear Registrant letter to pharmacy registrants, http://ppsconline.com/articles/2012/FL_PDAC.pdf.

of a pharmacist's professional practice. The obligation to identify any red flags relating to a controlled-substances prescription, to resolve them before filing the prescription, and to document any resolution of red flags is a well-recognized responsibility of a pharmacist in the professional practice of pharmacy. *United States of America v. Walmart Inc. et al.*, 1:20-cv-01744, (D. Del. Dec. 22, 2020). Former DEA diversion investigator Demetra Ashley confirmed this proposition in her testimony in a deposition in this MDL. And, as the Department of Justice's complaint alleges, when 'Walmart pharmacists failed to comply with their own professional pharmacy standards' in this respect, 'Walmart ... violated 21 C.F.R. § 1306.06.'" *United States of America v. Walmart Inc. et al.*, 1:20-cv-01744, (D. Del. Dec. 22, 2020).

94. Under the CSA, the duty to prevent diversion lies with the Chain Pharmacies, not the individual pharmacist. As such, although it acts through its agents, the pharmacy is ultimately responsible to prevent diversion, as described above.[14] Further, as described above, the obligations under the controlled-substances laws extend to any entity selling prescription opioids, whether it is the registration holder or not. It is unlawful for any person knowingly to distribute or dispense controlled substances other than in accordance with the requirements of the federal CSA and its implementing regulations, or in violation of state controlled substances laws and regulations. Chain pharmacies are responsible "persons" under the CSA. They also exert control over their agents, including the responsibility to ensure they comply with applicable laws and regulations in

[14] *The Medicine Shoppe; Decision and Order*, 79 FR 59504, 59515 (DEA Oct. 2, 2014) (emphasis added); *see also Holiday CVS, L.L.C., d/b/a CVS/Pharmacy Nos. 219 and 5195*; Decision and Order, 77 FR 62316-01 ("When considering whether a pharmacy has violated its corresponding responsibility, the Agency considers whether the entity, not the pharmacist, can be charged with the requisite knowledge."); *Top RX Pharmacy*; Decision and Order, 78 FR 26069, 62341 (DEA Oct. 12, 2012) (same); *cf. Jones Total Health Care Pharmacy LLC and SND Health Care LLC v. Drug Enforcement Administration*, 881 F.3d 82 (11th Cir. 2018) (revoking pharmacy registration for, *inter alia*, dispensing prescriptions that prescriptions presented various red flags, i.e., indicia that the prescriptions were not issued for a legitimate medical purpose without resolving red flags).

all dispensing of controlled substances. Pharmacy chains cannot absolve themselves of their own obligations by attempting to place unilateral responsibility on their agents.

95. In addition to their duties as distributors, the Chain Pharmacies also had a duty to design and implement systems to prevent diversion of controlled substances in their retail pharmacy operations. The Chain Pharmacies had the ability, and the obligation, to look for these red flags on a patient, prescriber, and store level, and to refuse to fill and to report prescriptions suggestive of potential diversion. They also have a crucial role in creating chain-wide systems to identify and avoid filling "prescriptions" that are not issued for a legitimate purpose or by a prescriber with a valid, current license.

96. Pharmacy Defendants' obligations extend to monitoring, and documenting, the steps they take in accessing state prescription drug monitoring programs, often referred to as "PDMPs." Yet, the Chain Pharmacies, upon information and belief, generally relied on their pharmacists' discretion in this area rather than setting forth requirements concerning PDMP searches and implementing systems, at least for many years, to track and document PDMP searches and their results.

97. The CSA requires distributors and pharmacies, along with other participants in the supply chain of controlled substances like opioids to: (a) limit sales within a quota set by the DEA for the overall production of controlled substances like opioids; (b) register to distribute opioids; (c) maintain effective controls against diversion of the controlled substances that they manufacture or distribute; and (d) identify suspicious orders of controlled substances and halt such sales.

98. To ensure that even drugs produced within quota are not diverted, federal regulations issued under the CSA mandate that all registrants "design and operate a system to disclose to the registrant suspicious orders of controlled substances." 21 C.F.R. § 1301.74(b).

Registrants are not entitled to be passive (but profitable) observers, but rather "shall inform the Field Division Office of the Administration in his area of suspicious orders when discovered by the registrant." *Id.* Suspicious orders include orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency. *Id.* Other indicia of potential diversion may include, for example, "[o]rdering the same controlled substance from multiple distributors."

99. These criteria are disjunctive and are not all inclusive. For example, if an order deviates substantially from a normal pattern, the size of the order does not matter and the order should be reported as suspicious. Likewise, a distributor need not wait for a normal pattern to develop over time before determining whether a particular order is suspicious. The size of an order alone, regardless of whether it deviates from a normal pattern, is enough to trigger the responsibility to report the order as suspicious. The determination of whether an order is suspicious depends not only on the ordering patterns of the particular customer but also on the patterns of the entirety of the customer base and the patterns throughout the relevant segment of the industry. For this reason, identification of suspicious orders serves also to identify excessive volume of the controlled substance being shipped to a particular region.

100. The DEA has testified in this MDL that:

- DEA registrants are required to block all suspicious orders of prescription opioids.
- Shipping a suspicious order is a *per se* violation of federal law.
- If a wholesale distributor blocks a suspicious order, they should terminate all future sales to that same customer until they can rule out that diversion is occurring.
- After the fact reporting of suspicious orders has never been in compliance with federal law.[15]

[15] *See* Prevoznik Dep. Vol II, April 18, 2019 (DEA 30(b)(6) designee).

101. Of course, due diligence efforts must also be thorough: "the investigation must dispel all red flags indicative that a customer is engaged in diversion to render the order non-suspicious and exempt it from the requirement that the distributor inform the DEA about the order. Put another way, if, even after investigating the order, there is any remaining basis to suspect that a customer is engaged in diversion, the order must be deemed suspicious and the Agency must be informed. Indeed, the DEA may revoke a distributor's certificate of registration as a vendor of controlled substances if the distributor identifies orders as suspicious and then ships them without performing adequate due diligence.

102. To comply with the law, wholesale distributors, including Defendants, must know their customers and the communities they serve. Each distributor must "perform due diligence on its customers" on an "ongoing [basis] throughout the course of a distributor's relationship with its customer." *Masters Pharms., Inc.*, 80 Fed. Reg. 55,418, 55,477 (DEA Sept. 15, 2015), *petition for review denied*, 861 F.3d 206 (D.C. Cir. 2017).

103. Pharmacy order data provides detailed insight into the volume, frequency, dose, and type of controlled and non-controlled substances a pharmacy typically orders. This includes non-controlled substances and Schedule IV controlled substances (such as benzodiazepines), which are not reported to the DEA, but whose use with opioids can be indicative of diversion.

104. As acknowledged in an article another chain pharmacy, CVS, published in the New England Journal of Medicine, "[p]harmacies have a role to play in the oversight of prescriptions for controlled substances, and opioid analgesics in particular." Mitch Betses, R.Ph., and Troyen Brennan, M.D., M.P.H., *Abusive Prescribing of Controlled Substances - A Pharmacy View*, N. ENGL. J. MED. 369;11, Sept. 12., 2013, at 989-991. The DEA has identified "both pharmaceutical

distributors and chain pharmacies as part of the problem" contributing to opioid abuse and related deaths. *Id.*

105. The Chain Pharmacies have a particular "advantage" in meeting their obligations under the CSA because these entities can use "aggregated information on all prescriptions filled at the chain" in order to examine "patterns" of opioids and other "high-risk drugs" and target "inappropriate prescribing." *Id*. at 990. For example, a chain pharmacy should properly use its chainwide dispensing data to identify "high risk prescribers" by "benchmarking" prescription data based on "several parameters," including "volume of prescriptions for high-risk drugs," "the proportion of the prescriber's prescriptions that were for such [high-risk] drugs, as compared with the volume and proportion for others in the same specialty and region," cash payment, ages of patients, and the prescriber's ratio of "prescriptions for noncontrolled substances with prescriptions for controlled substances." *Id*. This "[a]nalysis of aggregated data" from chain pharmacies can "target patterns of abuse," in the face of "the growing use of controlled substances and resulting illnesses and deaths." *Id.* Accordingly, as the article touts, "innovative use of transparent data is only prudent." *Id.*

106. As the above-cited article counseled, Defendants may not ignore red flags of illegal conduct and must use the information available to them to identify, report, and not fill prescriptions that seem indicative of diversion. That would include reviewing their own data, relying on their observations of prescribers, pharmacies, and customers, and following up on reports or concerns of potential diversion.

107. In addition to their duties as distributors, Defendants also had a duty to monitor and report suspicious activity in their retail pharmacy operations. Specifically, Defendants had a duty to analyze data and store-level information for known red flags such as (a) multiple prescriptions

to the same patient using the same doctor; (b) multiple prescriptions by the same patient using different doctors; (c) prescriptions of unusual size and frequency for the same patient; (d) orders from out-of-state patients or prescribers; (e) an unusual or disproportionate number of prescriptions paid for in cash; (f) prescriptions paired with other drugs frequently abused with opioids, like benzodiazepines, or prescription "cocktails"; (g) volumes, doses, or combinations that suggested that the prescriptions were likely being diverted or were not issued for a legitimate medical purpose.

108. The CSA also imposes important record-keeping obligations on pharmacies, including pharmacy chains. "[E]very registrant . . . dispensing a controlled substance or substances shall maintain, on a current basis, a complete and accurate record of each such substance . . . received, sold, delivered, or otherwise disposed of by him." 21 USC 827(a). "[A] registrant's accurate and diligent adherence to [its recordkeeping] obligations is absolutely essential to protect against the diversion of controlled substances." Paul H. Volkman, 73 FR 30,630, 30,644 (2008). An important component of an anti-diversion system is the documentation Chain Pharmacies possess. They must utilize their information to identify patterns of diversion and for auditing, training, and investigation of suspicious activity in an effort to prevent diversion of controlled substances.

109. According to law and industry standards, if a pharmacy finds evidence of prescription diversion, the Board of Pharmacy and DEA must be contacted.

110. As distributors and as pharmacies, Defendants have a duty, and are expected, to be vigilant in ensuring that controlled substances are delivered only for lawful purposes.

111. State and federal statutes and regulations reflect a standard of conduct and care below which reasonably prudent distributors and pharmacies would not fall. Together, these laws

and industry guidelines make clear that Defendants possess and are expected to possess, specialized and sophisticated knowledge, skill, information, and understanding of both the market for scheduled prescription opioids and of the risks and dangers of the diversion of prescription opioids when the supply chain is not properly controlled.

112. Further, these laws and industry guidelines make clear that Defendants have a responsibility to exercise their specialized and sophisticated knowledge, information, skill, and understanding to prevent the oversupply of prescription opioids and minimize the risk of their diversion into an illicit market.

113. The privilege of holding a license to distribute and dispense controlled substances comes with the responsibility of ensuring that the controlled substances distributed or sold are not diverted and/or subject to abuse and misuse. State and federal laws also have developed fairly uniform standards of practice across the country. It is both intuitive and understood that selling drugs for non-medical purposes, or drugs which the dispenser knows or should know present a significant risk for diversion falls outside the standards of care and is not a legitimate practice. As part of usual and customary practice, prescriptions must be evaluated and determined to be valid and issued for a legitimate medical purpose.

114. Pharmacies' evaluation process includes with what is known as “Drug Utilization Review” or “DUR.” This practice is both part of traditional roles and duties and codified in federal and state statutes. Notably, during the rulemaking practice for one authority, the Omnibus Budget [R]econciliation Act of 1990 (OBRA 90), a commenter suggested that instructions for compliance with prospective DUR should go to the pharmacist and not the pharmacy. In response, the government stated that “the instructions for compliance with prospective DUR should be directed to the pharmacies,” and that “[t]he owners or managers of pharmacies, as Medicaid providers, are

responsible for furnishing their staff with information pertaining to DUR." States, seeking to assure uniformity, have taken action to require the same mandates as this federal law. The DUR process includes looking at over-utilization, drug interactions and identifying abuse and misuse of dangerous drugs such as opioids. This process would have provided the Chain Pharmacies information about potential diversion as well.

115. Accordingly, states, including Florida, implemented Prescription Drug Monitoring Programs (PDMPs) such as E-FORCSE®, Florida's PDMP.

116. Additionally, Chain Pharmacies have operating systems and methods to store and retain prescription dispensing data and records. The information they possess must be readily retrievable, and they have an obligation to use it to identify patterns of diversion, conduct internal audits and training programs, investigate suspicious prescribers, patients, and pharmacists, and prevent diversion of controlled substances. Their hiring, training, and management of pharmacy personnel, and their supporting policies, procedures, and systems should and must promote public health and safety and assist in the identification and prevention of the diversion of controlled substances.

3. Defendants Were Aware of and Have Acknowledged Their Obligations to Prevent Diversion and to Report and Take Steps to Halt Suspicious Orders.

117. The regulations aim to create a "closed" system in order to control the supply and reduce the diversion of these drugs out of legitimate channels into the illicit market, while at the same time providing the legitimate drug industry with a unified approach to narcotic and dangerous drug control. Both because distributors handle such large volumes of controlled substances, and because they are uniquely positioned, based on their knowledge of their customers and orders, as the first line of defense in the movement of legal pharmaceutical controlled substances from legitimate channels into the illicit market, distributors' obligation to maintain effective controls to

prevent diversion of controlled substances is critical. Should a distributor deviate from these checks and balances, the closed system of distribution, designed to prevent diversion, collapses.

118. Defendants were well aware they had an important role to play in this system, and also knew or should have known that their failure to comply with their obligations would have serious consequences.

119. Indeed, the DEA has repeatedly informed Defendants about their legal obligations, including obligations that were so obvious that they simply should not have required additional clarification. As former DEA agent Joseph Rannazzisi recently explained during a deposition in this MDL:

> Q. Someone says "Don't steal," do you have to put in there "from a supermarket"?
>
> A. No.
>
> Q. Someone says "Don't trespass on the property," do you have to put "wearing tennis shoes"?
>
> A. No.
>
> Q. Next, you got asked: "Well, you never instructed the companies to keep their files." Do you remember that?
>
> A. Yes, sir.
>
> Q. Would old files be important in monitoring—in your ongoing monitoring? Would it be important that a company keep their files so that they can look back at them?
>
> A: Absolutely. That's the—the whole idea behind maintaining a due diligence file is you have a history of purchases. That way you could see what they're doing and where they're going with their purchases.

120. For example, it is not an effective control against diversion to identify a suspicious order, ship it, and wait as long as weeks to report it to law enforcement, potentially allowing those pills to be diverted and abused in the meantime.

121. During a 30(b)(6) deposition in this MDL, the DEA's Unit Chief of Liaison was asked whether the DEA made it "clear to industry that the failure to prevent diversion was a threat to public safety and the public interest." In response, he testified:

> Yes, I think it's established in 823 [the Controlled Substances Act] where it's part of our -- part of the registrant that is applying to be a registrant understands that they have to maintain effective controls . . . . they also know that these drugs themselves are scheduled controlled substances for a particular reason, because they're addictive, psychologically and physically they're addictive, so they know that these drugs have these properties within themselves. **So they would understand that these drugs are categorized or scheduled in that manner because they have the potential to hurt**.

122. And Defendants did understand. As described below, at least Walgreens has itself acknowledged (internally) its understanding of the potential consequences of its failure to report and cease shipping suspicious orders.

123. In fact, trade organizations in which Defendants have actively participated have acknowledged that distributors have been responsible for reporting suspicious orders for more than 40 years. The National Association of Chain Drug Stores ("NACDS") is a national trade association that represents traditional drug stores, supermarkets, and mass merchants with pharmacies—from regional chains with four stores to national companies. Its members and/or affiliate members also include stakeholders such as manufacturers, other distributors and other trade organizations as well. Most of the Defendants serve on the Board of Directors of NACDS. As controlling members of NACDS, Chain Pharmacy Defendants have served on and run key governing committees within the organization. Chain Pharmacies have repeatedly chaired NACDS's Board of Directors, which determines the "strategic plan and positions" of the organization. During the last 12 years, representatives of Walgreens has always held Board of Directors or officer seats. Publix is an NACDS member.

124. The Healthcare Distribution Management Association ("HDMA," now known as the Healthcare Distribution Alliance ("HDA"), and prior to 2000, known as the National Wholesale Druggists' Association ("NWDA")), is a national trade association representing distributors that has partnered with NACDS. The two groups viewed their relationship as a strategic "alliance."

125. In 2006, the NACDS issued a "Model Compliance Manual" intended to "assist NACDS members" in developing their own compliance programs. The Model Compliance Manual notes that a retail pharmacy may "generate and review reports for its own purposes" and refers to the assessment tools identified by CMS in its Prescription Drug Benefit Manual chapter on fraud, waste and abuse, including:

- Drug Utilization Reports, which identify the number of prescriptions filled for a particular customer and, in particular, numbers for suspect classes of drugs such as narcotics to identify possible therapeutic abuse or illegal activity by a customer. A customer with an abnormal number of prescriptions or prescription patterns for certain drugs should be identified in reports, and the customer and his or her prescribing providers can be contacted and explanations for use can be received.

- Prescribing Patterns by Physician Reports, which identify the number of prescriptions written by a particular provider and focus on a class or particular type of drug such as narcotics. These reports can be generated to identify possible prescriber or other fraud.

- Geographic Zip Reports, which identify possible "doctor shopping" schemes or "script mills" by comparing the geographic location (zip code) of the patient to the location of the provider who wrote the prescription and should include the location of the dispensing pharmacy.

126. In 2007 and 2008, the HDA began developing "Industry Compliance Guidelines" ("ICG") that aimed to outline certain "best practices" for distributors of controlled substances. As part of its development of the ICG, the HDA met with the DEA on at least three occasions. The HDA also sought extensive input from its membership, as well as other groups such as the Pain Care Forum. Internal discussions concerning the ICG further demonstrate the industry's

knowledge of what was expected of them. For example, when deciding whether or not the guidelines should permit a distributor to still ship a part of an order identified as suspicious, the HDA noted that one potential downside of this approach was that "DEA correspondence/interpretation do not support this practice."

127. The HDA released the ICG in 2008 and, in doing so, it emphasized that distributors were "[a]t the center of a sophisticated supply chain" and "uniquely situated to perform due diligence in order to help support the security of the controlled substances they deliver to their customers."[16]

128. More recently, in the appeal that arose from DEA's enforcement action against wholesaler Masters Pharmaceuticals, Inc. for its distribution of opioids, the HDA and NACDS submitted a joint amicus brief regarding the legal duty of distributors that acknowledged that "HDMA and NACDS members" had a duty to prevent diversion. *See Masters Pharmaceuticals, Inc. v. U.S. Drug Enforcement Admin.*, 2016 WL 1321983 (D.C. Cir. April 4, 2016). As described below, both the HDA and NACDS have both long taken the position that distributors have responsibilities to "prevent diversion of controlled prescription drugs" not only because they have statutory and regulatory obligations do so, but "as responsible members of society."

129. The requirement to report suspicious orders at the time (not after the fact) has always been clear and Defendants themselves have acknowledged as much through their various trade groups and associations. As described above, correspondence between the NWDA and the DEA, as early as 1984, illustrates that the DEA provided clear guidance well before the opioid

[16] Healthcare Distribution Management Association (HDMA) Industry Compliance Guidelines: Reporting Suspicious Orders and Preventing Diversion of Controlled Substances, filed in *Cardinal Health, Inc. v. Holder*, No. 12-5061 (D.C. Cir. Mar. 7, 2012), Doc. No. 1362415 (App'x B at 1).

crisis was unleashed. For example, in one letter to the NWDA, DEA Section Chief Thomas Gitchel emphasized that "the submission of a monthly printout of after-the-fact sales will not relieve a registrant from the responsibility of reporting excessive or suspicious orders," noting "**DEA has interpreted 'orders' to mean prior to shipment.**" Consistent with that understanding, the NWDA's 1984 Guidelines repeated the same directive.

130. In addition, the DEA, for example, in April 1987, sponsored a three-day "Controlled Substances Manufacturers and Wholesalers Seminar" that was attended by "over fifty security and regulatory compliance professionals representing forty-three major pharmaceutical manufacturers and wholesalers." According to the executive summary of the event, Ronald Buzzeo held a session on "excessive order monitoring programs," wherein he explained:

> [A]ny system must be capable of both detecting individual orders which are suspicious, or orders which become suspicious over time due to frequency, quantity, or pattern. The NWDA system, for example, provides an excellent lookback, or trend system, but the ability to identify one time suspicious orders should not be overlooked as an element of the program. Another area at issue was whether DEA would take action against a registrant which reported an order and then shipped it. DEA pointed out that the company is still responsible under their registrations for acting in the public interest. Reporting the order does not in any way relieve the firm from the responsibility for the shipment.

131. The DEA also repeatedly reminded Defendants of their obligations to report and decline to fill suspicious orders. Responding to the proliferation of internet pharmacies that arranged illicit sales of enormous volumes of opioids, the DEA began a major push to remind distributors of their obligations to prevent these kinds of abuses and educate them on how to meet these obligations.

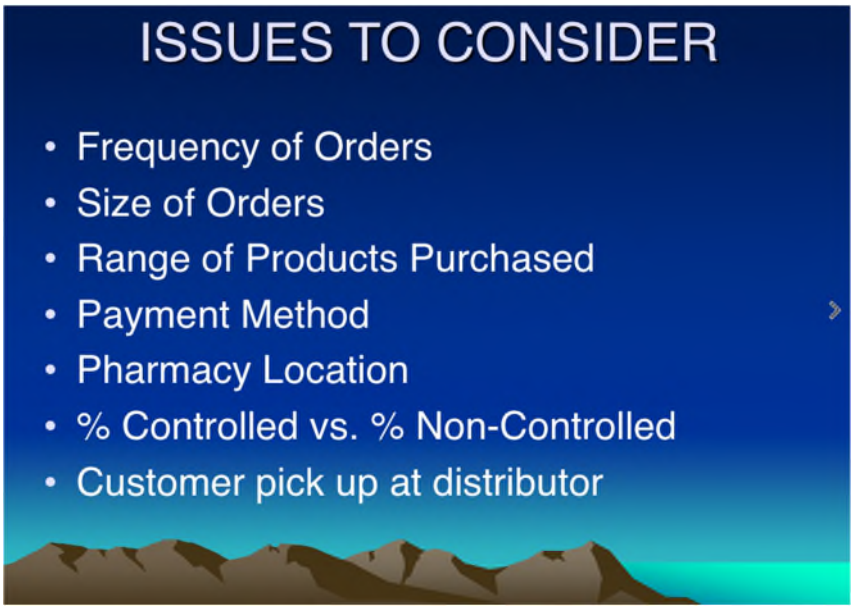
132. Specifically, in August 2005, the DEA's Office of Diversion Control launched the "Distributor Initiative." The Distributor Initiative did not impose any new duties on distributors, but simply reminded them of their duties under existing law. The stated purpose of the program

was to "[e]ducate and inform distributors/manufacturers of their due diligence responsibilities under the CSA by discussing their Suspicious Order Monitoring System, reviewing their [Automation of Reports and Consolidated Orders System ("ARCOS")] data for sales and purchases of Schedules II and III controlled substances, and discussing national trends involving the abuse of prescription controlled substances."[17] The CSA requires that distributors (and manufacturers) report all transactions involving controlled substances to the United States Attorney General. This data is captured in ARCOS, the "automated, comprehensive drug reporting system which monitors the flow of DEA controlled substances from their point of manufacture through commercial distribution channels to point of sale or distribution at the dispensing/retail level—hospitals, retail pharmacies, practitioners, mid-level practitioners, and teaching institutions,"[18] described above, from which certain data has now been made public.

133. As part of the Distributor Initiative, the DEA gave several presentations to distributors both individually and through presentations and discussions at Defendants' trade groups meetings directly targeted at some of the red flags of diversion that the Defendants were obligated to consider and monitor as part of their requirements under the law.

[17] Thomas W. Prevoznik, Office of Diversion Control, Distributor Initiative presentation (Oct. 22, 2013), https://www.deadiversion.usdoj.gov/mtgs/distributor/conf_2013/prevoznik.pdf.

[18] U.S. Dept. of Justice, Drug Diversion Administration, Diversion Control Division website, https://www.deadiversion.usdoj.gov/arcos/index.html.



134. The DEA has hosted many different conferences throughout the years, including Pharmacy Diversion Awareness Conferences, to provide registrants with updated information about diversion trends and their regulatory obligations. The DEA also frequently presented at various other conferences for registrants at the national, state, or local level.

135. Through presentations at industry conferences and on its website, the DEA provided detailed guidance to distributors on what to look for in assessing their customers' trustworthiness. As an example, the DEA published "Suggested Questions a Distributor Should Ask Prior to Shipping Controlled Substances"[19]

[19] U.S. Dept. of Justice, DEA, Diversion Control Division website, Pharmaceutical Industry Conference (Oct 14 & 15, 2009), *Suggested Questions a Distributor should ask prior to shipping controlled substances*, Drug Enforcement Administration *available at* https://www.deadiversion.usdoj.gov/mtgs/pharm_industry/14th_pharm/levinl_ques.pdf; Richard Widup, Jr., Kathleen H. Dooley, Esq., *Pharmaceutical Production Diversion: Beyond the PDMA*, Purdue Pharma and McGuireWoods LLC, *available at* https://www.mcguirewoods.com/news-resources/publications/lifesciences/product_diversion_beyond_pdma.pdf.

136. In addition, the DEA sent a series of letters, beginning on September 27, 2006, to every commercial entity registered to distribute controlled substances, including chain pharmacy distributors. The 2006 letter emphasized that distributors are:

> one of the key components of the distribution chain. If the closed system is to function properly . . . distributors must be vigilant in deciding whether a prospective customer can be trusted to deliver controlled substances only for lawful purposes. This responsibility is critical, as . . . the illegal distribution of controlled substances has a substantial and detrimental effect on the health and general welfare of the American people.[20]

137. The letter also warned that "even just one distributor that uses its DEA registration to facilitate diversion can cause enormous harm."[21]

138. The DEA sent a second letter to distributors on December 27, 2007. Again, the letter instructed that, as registered distributors of controlled substances, they must each abide by statutory and regulatory duties to "maintain effective controls against diversion" and "design and operate a system to disclose to the registrant suspicious orders of controlled substances."[22] DEA's letter reiterated the obligation to detect, report, and not fill suspicious orders and provided detailed guidance on what constitutes a suspicious order and how to report (*e.g.*, by specifically identifying an order as suspicious, not merely transmitting ARCOS data to the DEA).

---

[20] Letter from Joseph T. Rannazzisi, Deputy Assistant Adm'r, Off. of Diversion Control, Drug Enf't Admin., U.S. Dep't of Justice, to Cardinal Health (Sept. 27, 2006), filed in *Cardinal Health, Inc. Inc. v. Holder*, No. 1:12-cv-00185-RBW (D.D.C. Feb. 10, 2012), ECF No. 14-51 ("2006 Rannazzisi Letter"); *see also* WAGMDL00757797.

[21] *Id.*

[22] Letter from Joseph T. Rannazzisi, Deputy Assistant Adm'r, Office of Diversion Control, Drug. Enf't Admin., U.S. Dep't of Justice, to Cardinal Health (Dec. 27, 2007), filed in Cardinal Health, Inc. v. Holder, No. 1:12-cv00185-RBW (D.D.C. Feb. 10, 2012), ECF No. 14-8 ("2007 Rannazzisi Letter").

139. In September 2007, the NACDS, among others, also attended a DEA conference at which the DEA reminded registrants that not only were they required to report suspicious orders, but also to halt shipments of suspicious orders. Walgreens, specifically, registered for the conference.

140. The DEA's regulatory actions against the three largest wholesale distributors further underscore the fact that distributors such as Defendants were well aware of their legal obligations. There is a long history of enforcement actions against registrants for their compliance failures. For example, in 2007, the DEA issued an Order to Show Cause and Immediate Suspension Order against three of Cardinal Health's distribution centers, and on December 23, 2016, Cardinal Health agreed to pay the United States $44 million to resolve allegations that it violated the CSA in Maryland, Florida, and New York. Similarly, on May 2, 2008, McKesson entered into an Administrative Memorandum of Agreement ("AMA") with the DEA related to its failures in maintaining an adequate compliance program. Subsequently, in January 2017, McKesson entered into an AMA with the DEA wherein it agreed to pay a $150 million civil penalty for, *inter alia*, failure to identify and report suspicious orders at several of its facilities.

141. The DEA has also repeatedly affirmed the obligations of pharmacies to maintain effective controls against diversion in regulatory action after regulatory action.[23] The DEA, among

[23] *See, e.g.*, Holiday CVS, L.L.C., d/b/a CVS/Pharmacy Nos. 219 and 5195; 77 Fed. Reg. 62,316 (DEA Oct. 12, 2012) (decision and order); East Main Street Pharmacy, 75 Fed. Reg. 66,149 (DEAOct. 27, 2010) (affirmance of suspension order); Holiday CVS, L.L.C. v. Holder, 839 F.Supp.2d 145 (D.D.C. 2012); Townwood Pharmacy; 63 Fed. Reg. 8,477 (DEA Feb. 19, 1998) (revocation of registration); Grider Drug 1 & Grider Drug 2; 77 Fed. Reg. 44,069 (DEA July 26, 2012) (decision and order); The Medicine Dropper; 76 Fed. Reg. 20,039 (DEA April 11, 2011) (revocation of registration); Medicine Shoppe-Jonesborough; 73 Fed. Reg. 363 (DEA Jan. 2, 2008) (revocation of registration).

others, also has provided extensive guidance to pharmacies on how to identify suspicious orders and other evidence of diversion.

142. DEA has repeatedly emphasized that retail pharmacies, such as Defendants, are required to implement systems that detect and prevent diversion and must monitor for and report red flags of diversion. When red flags appear, the pharmacy's "corresponding responsibility" under 21 C.F.R. § 1306.04(a) requires it either to take steps (and document those steps) to resolve the issues or else to refuse to fill prescriptions with unresolvable red flags.[24] DEA has identified several types of "unresolvable red flags" which, when present in prescriptions presented to a pharmacist, may never be filled by the overseeing pharmacist. These unresolvable red flags include: a prescription issued by a practitioner lacking valid licensure or registration to prescribe the controlled substances; multiple prescriptions presented by the same practitioner to patients from the same address; prescribing the same controlled substances in each presented prescription; a high volume of patients presenting prescriptions and paying with cash; and, a prescription presented to by a customer who has traveled significant and unreasonable distances from their home to see a doctor and/or to fill the prescription at the pharmacy.

143. DEA guidance also instructs pharmacies to monitor for red flags that include: (1) prescriptions written by a doctor who writes significantly more prescriptions (or in larger quantities or higher doses) for controlled substances as compared to other practitioners in the area, and (2) prescriptions for antagonistic drugs, such as depressants and stimulants, at the same time. Most of the time, these attributes are not difficult to detect and should be easily recognizable by Defendants' diversion control systems.

[24] *Pharmacy Doctors Enterprises, Inc. v. Drug Enf't Admin.*, No. 18-11168, 2019 WL 4565481, at *5 (11th Cir. Sept. 20, 2019).

144. In 2011, the DEA took Walgreens "to the woodshed" over its dispensing cocktail drugs and opioids to questionable out of state customers, customers with the duplicate diagnoses, young people, and customers only paying cash. Many of these same red flags were highlighted in the 2009 Walgreens Order to Show Cause and resulting 2011 Memorandum of Agreement.

145. As another example, in a 2016 presentation to the American Pharmacists Association, the DEA reiterated that retail pharmacies must watch for red flags such as: large numbers of customers who: receive the same combination of prescriptions, receive the same strength of controlled substance prescription (often for the strongest dose), have prescriptions from the same prescriber, and have the same diagnosis code.

146. Red flags are common sense warning signs that have always been an important component of controlled substance pharmacy best practices, not a novel concept to pharmacies. Relevant guidance concerning narcotics dispensing dates back to at least since the 1930's and 1940's there has been guidance given to pharmacies and pharmacists related to the creation of systems and programs to guard against diversion and lists of don'ts when dispensing narcotics. DEA enforcement actions such as the *Holiday* decision, *Medicine Shoppe-Jonesborough* and *United Prescription Services, Inc.* also hold pharmacies responsible for failing to fulfill their corresponding responsibility under the CSA.

147. Certain of the Chain Pharmacies, including Walgreens, and their trade organizations, including the NACDS, also participated in creating a "Stakeholders" memorandum that acknowledges many of these red flags. These include for example, traveling unexplainable and/or unreasonably long distance to a physician office and/or the pharmacy, a controlled substance refill pattern inconsistent with regular refill patterns for non-controlled substances, or a prescription that a pharmacist knows or reasonably believes another pharmacy refused to fill. The

"Stakeholders" memorandum acknowledges the danger of "therapeutic duplication of two or more long-acting and/or two or more short-acting opiates (cocktails)" and "patient presents prescriptions for highly abused 'cocktails' (combination of opiate, benzodiazepine, and muscle relaxant) of controlled substance medications (cocktails)." The "cocktail" often referred to as the "Holy Trinity" consists of an opioid, a benzodiazepine, and a muscle-relaxer such as carisoprodol. A "trinity" combination can also refer to different combinations of opioid/non-opioid prescriptions intended for abuse and to create a euphoric feeling similar to heroin and other illicit drugs. Medical literature has long recognized the special dangers posed by cocktails composed of drugs of abuse which lack any documented medical efficacy." Similarly, the *East Main Street Pharmacy* action acknowledged that "the combination of a benzodiazepine, a narcotic and carisoprodol is well known in the pharmacy profession as being used by patients abusing prescription drugs."

148. As a DEA administrative decision from 2008 explains, "[w]hile carisoprodol [was] not controlled under Federal law, it is controlled under various state laws and is highly popular with drug abusers, especially when taken as part of a drug cocktail that includes an opiate and a benzodiazepine." *See Your Druggist Pharmacy*, 73 Fed. Reg. 75,774, 75,775 n.1 (DEA Dec. 2008). Other DEA and judicial decisions likewise acknowledge well-known and highly abused cocktails. *See, e.g., U.S. v. Evans*, 892 F.3d 692, 706 (5th Cir. 2018).

149. As described above, red flags indicative of diversion include suspicious behavior of patients, such as stumbling while walking, slurred speech, appearance of intoxication, or of customers coming and appearing like they may not need the medication, or requesting drugs by brand name or street slang such as "blues" (a term referencing Mallinckrodt opioids). Pharmacies' training materials and controls should assist pharmacists and technicians in the identification of such behaviors.

150. Pharmacies must resolve red flags before a prescription for addictive and dangerous drugs, such as opioids, are dispensed.

4. Defendants Were Uniquely Positioned to Guard Against Diversion

151. Not only do Chain Pharmacies often have firsthand knowledge of dispensing red flags – such as distant geographic location of doctors from the pharmacy or customer, lines of seemingly healthy patients, cash transactions, and other significant information – but they also have the ability to analyze data relating to drug utilization and prescribing patterns across multiple retail stores. As with other distributors, these data points give the Chain Pharmacies insight into prescribing and dispensing conduct that enables them to prevent diversion and fulfil their obligations under the CSA.

152. Chain Pharmacies not only make observations through their local front doors, but have extensive data to which an individual pharmacist would not have access. They are uniquely positioned to monitor, for example, the volume of opioids being dispensed in their pharmacies relative to the size of the communities they serve. This is particularly important given that it is recognized that as to the supply of opioids increases, so does the incidence of over-dose and death. They could also use this information to monitor potentially suspicious prescribers. Pharmacies must use the information available to them to guard against supplying controlled substances for non-medical use, identify red flags or potential diversion and should share this information with their agents, as well as provide clear guidance and training on how to use it. A former DEA diversion investigator, whose testimony is also referenced above, agreed in a deposition in this MDL that as part of their obligation under Section 1301.71, pharmacies corporately have an obligation to develop policies to train pharmacists to comply the CSA regulations. She further agreed that the defendants had an obligation to develop and implement systems to provide the necessary tools for their pharmacists to comply with the CSA regulations.

153. As explained above, in addition to their duties as distributors, the Chain Pharmacies also had a duty to design and implement systems to prevent diversion of controlled substances in their retail pharmacy operations. Specifically, the Chain Pharmacies had a duty to analyze data and the personal observations of their employees for known red flags such as those described above. The Chain Pharmacies had the ability, and the obligation, to look for these red flags on a patient, prescriber, store, and chain level, and to refuse to fill and to report prescriptions that suggested potential diversion.

154. They were particularly well-positioned to do so given the dispensing data available to them, which they could review at the corporate level to identify patterns of diversion and to create policies and practices to proactively identified patterns of diversion. Each could and should have also developed tools and programs to alert their pharmacists to red flags and to guard against diversion.

155. As described above and further below, the Chain Pharmacies also possessed sufficiently detailed and valuable information that other companies were willing to pay them for it. In 2010, for example, Walgreen's fiscal year 2010 SEC Form 10-K disclosed that it recognizes "purchased prescription files" as "intangible assets" valued at $749,000,000.[25] In addition, Walgreens's own advertising has acknowledged that Walgreens has centralized data such that customers' "complete prescription records" from Walgreens's "thousands of locations nationwide" are "*instantly available.*"

156. Each of the Chain Pharmacies had complete access to all prescription opioid dispensing data related to its pharmacies in the City, complete access to information revealing the doctors who prescribed the opioids dispensed in its pharmacies in and around the City, and

[25] https://www.sec.gov/Archives/edgar/data/104207/000010420710000098/exhibit_13.htm

complete access to information revealing the customers who filled or sought to fill prescriptions for opioids in its pharmacies in and around the City. Each of the Chain Pharmacies likewise had complete access to information revealing the customers who filled or sought to fill prescriptions for opioids in its pharmacies in and around the City, complete access to information revealing the opioids prescriptions dispensed by its pharmacies in and around the City, and complete access to information revealing the opioids prescriptions dispensed by its pharmacies in and around the City. Further, each of the Chain Pharmacies had complete access to information revealing the geographic location of out-of-state doctors whose prescriptions for opioids were being filled by its pharmacies in and around the City and complete access to information revealing the size and frequency of prescriptions written by specific doctors across its pharmacies in and around the City.

5. Defendants Failed to Maintain Effective Controls Against Diversion.

157. As described further below, the Chain Pharmacies failed to fulfill their legal duties and instead, routinely distributed and/or dispensed controlled substances while ignoring red flags of diversion and abuse. The unlawful conduct by these Defendants is a substantial cause for the volume of prescription opioids and the public nuisance plaguing the City.

a. Walgreens

158. Acting as both a distributor and a retail pharmacy chain, Walgreens self-distributed opioids to its own individual Walgreens pharmacies. Although Walgreens had visibility into indicia of diversion due to its vertically integrated distribution and dispensing practices, it failed to take these factors into account in its SOM program during the vast majority of the time it was distributing prescription opioids. Moreover, its program was wholly inadequate and did not fulfill its duties to prevent diversion. Likewise, Walgreens also failed to maintain effective controls against diversion from its pharmacy stores.

i. Walgreens Dragged Its Feet on Developing a SOM Program, Instead Relying on After-the-Fact Reports of "Excessive" Orders While Ignoring Red Flags

159. Though Walgreens had access to significant information about indicia of diversion due to its vertical integration with its stores, Walgreens failed to use available information to monitor and effectively prevent diversion.

160. At least as early as 1998, and perhaps as early as 1988, Walgreens began to utilize a series of formulas to identify orders that Walgreens deemed to be suspicious based on the orders' extraordinary size. These orders were listed on a report called the Suspicious Control Drug Order report.

161. Walgreens used two different formulas: one formula from (at least) 1998-2007 and one formula from March 2007 through 2012. These formulas were alike in that they each utilized an average number based on historical orders, applied a three times multiplier to that base number, and then deemed certain orders which were greater than that number to be suspicious. Under the later formula, orders were only listed on the report as being suspicious if the orders exceeded the three times multiplier for two consecutive months in a given time period. Walgreens based this second formula on the DEA's Chemical Handler's Manual's order monitoring system for listed chemicals.

162. The first variation on this formula was in place until March 2007, even though the DEA warned Walgreens that the "formulation utilized by the firm for reporting suspicious ordering of controlled substances was insufficient," *via* a May 2006 Letter of Admonition. The Letter cited Walgreens for controlled substances violations at its Perrysburg, Ohio Distribution Center, but highlighted problems that went far beyond that particular facility.

163. The DEA also reminded Walgreens that its suspicious ordering "formula should be based on (size, pattern, frequency)," though Walgreens failed to even examine anything other than

the size of an order. When Walgreens did update its program some ten months later, however, it still did not perform the size, pattern, and frequency analysis prescribed by the DEA, continuing to use another "three times" formula. [redacted]

164. Even with its ample threshold, each Walgreens Suspicious Control Drug Order report could be thousands of pages or more in length.

165. Walgreens did not perform any due diligence on the thousands of orders identified as "suspicious" on the Suspicious Control Drug Order reports, but instead shipped the orders without review.

166. Walgreens did not report the suspicious orders listed on the Suspicious Control Drug Order report until *after* the orders were already filled and shipped. The report was generated on a monthly, nationwide basis, directly contravening the regulatory requirement that suspicious orders be reported *when discovered.* 21 C.F.R. 1301.74(b). In some instances, months may have elapsed between an order's shipment and its subsequent reporting to the DEA, given the requirement, described above, of two consecutive months of exceeding the three times multiplier to trigger reporting.

167. In September 2010, a pharmacist who worked at a Walgreens pharmacy in Ft. Pierce, which also received shipments from the Jupiter Center, contacted law enforcement after mistakenly providing an additional 120 doses of 15 milligram oxycodone to a customer. When the pharmacist contacted the customer to ask that he return the opioids, he spoke with his girlfriend who said that the customer was addicted to drugs and also sells his prescription drugs. She also explained that he would not return the drugs. Despite this incident, the pharmacy continued to

provide several additional prescriptions of oxycodone to the customer, all of which were supplied by the Jupiter Center.

168. The Jupiter Center, along with Defendant Walgreens' headquarters, ignored warnings and concerns from its own employees about large shipments of opioids. In January 2011, the Center's Function Manager, who was responsible for all Schedule II drug operations (including opioids), sent an email to the manager of Walgreens' drug stores at its headquarters about the suspiciously "large quantity," of oxycodone that was being ordered by three stores in Florida. The Jupiter Center continued to supply opioids to these locations, and provided a Walgreens' pharmacy in Port Richey, a town of less than 3,000 people, 285,800 30 milligram doses of oxycodone in January 2011. Despite the warning from an employee, Defendant Walgreens did not report any of these orders as suspicious.

169. In September 2012, the DEA issued an immediate suspension order ("ISO") regarding one of Walgreens's three Schedule II distribution centers, finding Walgreens's distribution practices constituted an "imminent danger to the public health and safety" and were "inconsistent with the public interest." The DEA further found that Walgreens's Jupiter distribution center failed to comply with DEA regulations that required it to report to the DEA suspicious drug orders that Walgreens received from its retail pharmacies, resulting in at least tens of thousands of violations, particularly concerning massive volumes of prescription opiates. There, the DEA stated: "Notwithstanding the ample guidance available, Walgreens has failed to maintain an adequate suspicious order reporting system and as a result, has ignored readily identifiable orders and ordering patterns that, based on the information available throughout the Walgreens Corporation, should have been obvious signs of diversion occurring at [its] customer pharmacies."

170. In the ISO, the DEA also specifically considered the Suspicious Control Drug Order reports and made the following further findings of fact and conclusions of law regarding the reports and Walgreens's suspicious order monitoring system—applicable across Walgreens's operations:

- "[Walgreens's] practice with regard to suspicious order reporting was to send to the local DEA field office a monthly report labeled 'Suspicious Control Drug Orders.'"

- "[The Suspicious Control Drug] reports, consisting of nothing more than an aggregate of completed transactions, did not comply with the requirement to report suspicious orders as discovered, despite the title [Walgreens] attached to these reports."

- Upon review of an example of the Suspicious Control Drug Order report for December 2011, "[Walgreens's] suspicious order report for December 2011 appears to include suspicious orders placed by its customers for the past 6 months. The report for just suspicious orders of Schedule II drugs is 1712 pages and includes reports on approximately 836 pharmacies in more than a dozen states and Puerto Rico."

- Finding that the reports failed to appropriately consider the population and area being served by the pharmacy: "This report from the Jupiter [Florida] Distribution Center covers pharmacies in multiple states and Puerto Rico, yet the average order and trigger amount is the same for a particular drug regardless of the pharmacy's location, the population it serves, or the number of other pharmacies in the area."

- "As made clear in 21 CFR§ 1301.74(b), *Southwood,* and the December 27, 2007 letter to distributors from the Deputy Assistant Administrator for the Office of Diversion Control, suspicious orders are to be reported *as discovered,* not in a collection of monthly completed transactions. Moreover, commensurate with the obligation to identify and report suspicious orders as they are discovered is the obligation to conduct meaningful due diligence in an investigation of the customer and the particular order to resolve the suspicion and verify that the order is actually being used to fulfill legitimate medical needs. This analysis must take place *before* the order is shipped. No order identified as suspicious should be fulfilled until an assessment of the order's legitimacy is concluded."

- "DEA's investigation of [Walgreens] ... revealed that Walgreens failed to detect and report suspicious orders by its pharmacy customers, in violation of 21 C.F.R. §1301.74(b). 21 C.F.R. § 1301.74(b)."

- ". . . DEA investigation of [Walgreens's] distribution practices and policies ... demonstrates that [Walgreens] has failed to maintain effective controls

> against the diversion of controlled substances into other than legitimate medical, scientific, and industrial channels, in violation of 21 U.S.C. *55* 823(b)(l and (e)(l). [Walgreens] failed to conduct adequate due diligence of its retail stores, including but not limited to, the six stores identified above, and continued to distribute large amounts of controlled substances to pharmacies that it knew or should have known were dispensing those controlled substances pursuant to prescriptions written for other than a legitimate medical purpose by practitioners acting outside the usual course of their professional practice. . . . [Walgreens has not] recognized and adequately reformed the systemic shortcomings discussed herein."

- "[DEA's] concerns with [Walgreens'] distribution practices are not limited to the six Walgreens pharmacies [for which DEA suspended Walgreens' dispensing registration]."

ii. Walgreens Knew its After-the-Fact Excessive Purchase Reports Failed to Satisfy Its Obligations to Identify, Report, and Halt Suspicious Orders

171. Walgreens knew its procedures were inadequate well before the 2012 ISO issued. In addition to the guidance described above, in 1988, the DEA specifically advised Walgreens that "[t]he submission of a monthly printout of after-the-fact sales does *not* relieve the registrant of the responsibility of reporting excessive or suspicious orders." The DEA further advised Walgreens that, while "[a]n electronic data system may provide the means and mechanism for complying with the regulations...the system is not complete until the data is carefully reviewed and monitored by the registrant."

172. Despite this instruction, there is no evidence that Walgreens ever took any action related to the Suspicious Control Drug Order report besides generating it and mailing it out. Walgreens has admitted that there is no evidence that Walgreens ever performed a due diligence review on any of the orders listed on the Suspicious Control Drug Order report before shipment. One of the managers for Walgreens's Pharmaceutical Integrity ("RX Integrity") Department stated that, when he was with the Loss Prevention Department, he "basically burned the data on a CD and sent it off. I didn't dive into each individual report or CD" and that he "would look at it briefly,

but just to see if the data transferred to the CD, but that's about the extent." In an errata submitted in connection with a deposition in the MDL, Walgreens acknowledged that it "is currently unaware of due diligence that was performed based on orders being flagged . . ."

173. As described above, in May 2006, the DEA told Walgreens again that the formula Walgreens was using to identify suspicious orders for the Suspicious Control Drug Order reports was "insufficient" and "inadequate."

174. Moreover, in September 2007, three Walgreens's senior employees (Dwayne Pinon, Senior Attorney; James Van Overbake, Auditor; and Irene Lerin, Audit Manager) attended the DEA Office of Diversion Control's 13th Pharmaceutical Industry Conference in Houston, Texas. Michael Mapes, Chief, DEA, Regulatory Section, gave a presentation at this Conference relating to suspicious orders, which included the reminder that the CSA "requirement is to report suspicious orders, not suspicious sales after the fact." Participant notes from this meeting indicate that Mr. Mapes advised the audience not to "confuse suspicious order report with an excessive purchase report. They are two different things."

175. Similarly, handwritten notes on an internal document from July 2008 state that "DEA really wants us to validate orders and only report true suspicious orders or what was done to approve orders." They go on to state that "[j]ust reporting these orders is not good enough – need to document what happened."

176. Though Walgreens claims that it implemented the three times formula based on DEA guidance, DEA never approved Walgreens's SOM system, or any use of the Appendix E-3 formula, during the course of DEA's cyclic or scheduled investigations of Walgreens's distribution centers. As DEA 30b6 witness Clare Brennan testified, while DEA investigators are trained to ensure a SOM system is in place, they are also trained not to approve any SOM system. This non-

approval, the impropriety of any attempt by Walgreens to rely on prior purported approval, and the compliance failures of Walgreens's then utilized system, were re-emphasized by the letter Walgreens—and all controlled substance distributors—received from the DEA in 2007.

177. [redacted]

178. [redacted]

179. [redacted]

180. [redacted]

181. [redacted]

182. The Walgreens controlled substances Distribution Center personnel who spoke to the DEA during the DEA's inspections of Walgreens's controlled substances distribution centers did not recall ever telling the DEA that Walgreens internally determined that Walgreens's SOM system contained no monitoring process, that the SOM system did not stop suspicious orders from being shipped, that Walgreens could be filling illicit orders, or that the orders Walgreens was reported to the DEA as suspicious had already been shipped.

183. Additionally, in November 2012, the Walgreens's Divisional Vice President of Pharmacy Services reported to Kermit Crawford, Walgreens's President of Pharmacy, Health and Wellness, his notes from meeting with the DEA about reporting suspicious orders, which included the note, "[i]f suspicious - you don't ship."

iii. Walgreens Lacked Meaningful Additional Systems to Address the Failures in Its System of After-the-Fact Reporting of Certain Orders

184. Walgreens nominally employed additional procedures within its distribution centers; however, these systems did not address the failings of the Suspicious Control Drug Order reports. These distribution center systems were not designed to detect suspicious orders of controlled substances, but rather were designed to detect typos or errors in order entry by the stores. Walgreens admits that its Distribution Centers are "more akin to supply warehouses," are "not designed to be a backstop to pharmacists," and that they are not well "equipped to ensure compliance" or to "assist in combatting controlled substance abuse," and "do not have the ability to detect trends in local markets."

185. The Distribution Center ("DC") level procedures are documented in a 2006 Questionable Order Quantity policy, which had two facets: first, it instructed DC personnel to review orders and contact the pharmacy with questions regarding quantities. The policy did not mention reporting suspicious orders until 2010, when it was updated to state that the Corporate

Office Internal Audit Department would handle suspicious store orders and inquiries. There is no evidence that the Internal Audit department had any involvement in reporting suspicious orders.

186. The second aspect of this DC level procedures required "pickers," the DC personnel who actually retrieved pill bottles off the shelves and placed them into totes for shipping, to look for "questionable" orders while picking.

187. The only review of the orders identified by the DC level procedures was calling the pharmacy to make sure the order had not been entered in error. Walgreens admitted this procedure was not intended to detect suspicious orders.

188. There is no evidence that any orders were ever reported as suspicious or halted as a result of Walgreens's distribution-center level policies. There is no evidence these procedures resulted in timely reporting of, due diligence on, or non-shipment of any order, including those listed as being "suspicious" on the Suspicious Control Drug Order reports.

189. Walgreens's documents effectively acknowledge that these were not true anti-diversion measures, and it recognized internally that it did not begin creating a SOM system until March 2008. Specifically, in March 2008, Walgreens finally formed a five department "team" to "begin creating" a SOM program. The new SOM program was not piloted until more than a year later, in August 2009, and even then, the pilot included orders form just seven stores. Not until September 2010 would the program, implemented in pieces and phases, be rolled out chain-wide, and from that point it took several more years to fully implement.

190. Through 2012, Walgreens continued to populate the Suspicious Control Drug Order report with thousands of orders that exceeded Walgreens's "three times" test, showing that Walgreens's post-2009 SOM program did little to mitigate the extraordinary volume of controlled substances being shipped by Walgreens to its pharmacies.

iv. Even as it Rolled Out its New SOM Program, Walgreens Left Significant Gaps and Loopholes in Place and Failed to Report and Perform Due Diligence on Orders It Flagged

191. Walgreens did not prioritize compliance when instituting its SOM system. MDL testimony from the Senior Director of the Walgreen's Pharmaceutical Integrity Department, which is charged with supervising Walgreens's SOM system, revealed that even as late as 2012, 2013, and 2014, Walgreens's viewed the SOM system as an inventory control mechanism rather than as a compliance control mechanism:

> Q: Now, Walgreens's system, similar to my alarm, is there to detect a potential red flag. Would you agree with that?
>
> A: It was put in place to ensure that the stores had the proper quantities. Not necessarily to . . . detect a red flag. The whole idea was to make sure that the stores were getting the quantities that they needed based on their peer group.

192. Perhaps because keeping supply moving, as opposed to preventing diversion, was Walgreens's primary focus, the SOM program Walgreens slowly developed had significant gaps or loopholes. For example, for the first few years, the program did not include orders that Walgreens stores were also placing to outside vendors, like Cardinal and AmerisourceBergen, allowing stores to order opioids from Walgreens distribution centers and from Cardinal and AmerisourceBergen, effectively permitting double dipping. It also did not prevent stores from placing an order to an outside vendor if the store attempted to place the order to a Walgreens DC, but was rejected by the new SOM system.

193. The new SOM-lite system also allowed Walgreens's stores to transfer controlled substances between stores and did not review these transfers (known as "interstores") within the SOM program, so that these transfers were not factored into SOM analytics. Additionally, stores could also place ad hoc "PDQ" ("pretty darn quick") orders for controlled substances outside of

their normal order days and outside of the SOM analysis and limits. Walgreens could even remove a store entirely from SOM review.

194. Further, although the new SOM algorithm identified more than 389 pages of suspicious orders per week as of August 2010, it failed to identify all the orders that Walgreens had marked as suspicious under its "three times" formulas and previously listed on its Suspicious Control Drug Order reports and submitted to the DEA "on a monthly basis." This "discrepancy" prompted an internal email from an employee in Walgreens's Loss Prevention Department, to Walgreens's Vice President, Distribution Centers and Logistics, suggesting that "the new system should be tested further and enhanced to provide broader coverage of controlled substance activity. The same e-mail stated that "we are not equipped to handle the 389+ pages of ADR4 [suspicious order monitoring] data which are compiled nationwide each week," and asked if his department had "a resource available" to assist. An email in response "recall[ed] the old paper report as being inches thick" and an instruction "in 1985 not to review or contact anyone on the data," and inquired, among other things, "[w]ho from your group has been reviewing the data collected for the past twenty-five years?" and "[a]t present is anyone doing any review on what would be considered suspicious quantities that are physically ordered and are releasing to stores?"

195. Starting in 2010, certain orders that exceeded store-based limits imposed by Walgreens's new SOM system were reduced to the store limit and shipped out. These orders were not reported to the DEA as suspicious, nor were they halted for review. The DEA found that Walgreens's policy of reducing and then filling and shipping suspicious orders without reporting them violated the law:

> This policy ignores the fact that the reporting requirement of 21 CFR § 1301.74(b) applies to *orders*, not shipments. A suspicious order placed by a customer pharmacy is made no less suspicious by application of a system designed to reduce or eliminate such orders

> prior to shipping. Construing the regulation this way defeats the essential purpose of the suspicious order requirement, which, as I stated in *Southwood,* is "to provide investigators in the field with information regarding potential illegal activity in an expeditious manner." 72 FR at 36501.

196. Walgreens's post-2009 SOM system flagged thousands of items per month as being suspicious. Internal Walgreens documents indicate that, in July 2011 alone, as many as 20,699 orders for controlled substances were "marked suspicious" by the new algorithm. However, very few of these orders received any review, and any review performed was nominal at best. Meanwhile, Walgreens failed to adequately staff the program and to train its employees regarding its requirements.

197. Walgreens cited two people as being primarily responsible for performing due diligence on suspicious orders in the 2009-2012 time period under the new SOM system. The first was a representative from the Loss Prevention department who said her department was "not equipped" to handle review and data analysis for the hundreds of pages of reports being compiled nationwide each week. The second was Barbara Martin, who estimated that she spent somewhere between one and three hours a week reviewing suspicious orders, reviewing only between 10 to 100 of the thousands of orders that were deemed suspicious under the new algorithm. Walgreens did not provide Ms. Martin access to information about the area the store was serving, the order history for comparable stores, or any other data beyond the sales and order history for that store. If an order did not "make sense" to her based on those limited resources, she testified that she would call the store or district manager or pharmacy supervisor. She lacked authority to take "direct action" on an order.

198. Walgreens has previously cited to a series of email exchanges with Ms. Martin and her deposition testimony as exemplars of its due diligence procedures under the post-2009 SOM program. In the emails, which date from January 10–11, 2011, and are between Ms. Martin and a

Walgreens DC employee, the DC employee notes that "several stores that are ordering huge quantities of 682971 [30 mg oxycodone] on a regular basis." The DC employee continued, with respect to a single store, "we have shipped them 3271 bottles [of 30 mg oxycodone] between 12/1/10 and 1/10/11. I don't know how they can even house this many bottles to be honest. How do we go about checking the validity of these orders?" Ms. Martin noted that the store had average weekly sales of 36,200 dosage units, which was equal to 362 bottles per week, stating, "I have no idea where these stores are getting this type of volume. The last pharmacy I was manager at did about 525 rxs/day and we sold about 500 tabs a month (5 bottles)." Ms. Martin then told the DC employee that she could call the district pharmacy supervisor to see if he "may be able to shed some light on the subject." Despite the fact that questions had been raised about this store ordering volume in January 2011, the very next month, Walgreens filled and shipped orders totaling another 285,800 dosage units of 30 milligram oxycodone to the same pharmacy, which was located in a town of less than 3,000 people.

199. In her deposition, Ms. Martin stated that she never even attempted to determine the size of the community that was receiving these "huge quantities" of oxycodone. She further testified that she was not near that store, did not have access to the store's prescriptions or patient information, and as noted above, couldn't take any "direct action." Approximately 18 months after this email exchange, as a result of DEA action, Walgreens agreed to surrender its DEA registration for this same store that Ms. Martin reviewed as part of her exemplary "due diligence."

200. In the ISO regarding the Distribution Center, the DEA found specifically regarding the orders that were the subject of these email exchanges, that "[b]ased on the evidence available to DEA, none of these orders were reported to DEA as suspicious and all appear to have been shipped, without any further due diligence to verify their legitimacy." The DEA further found

regarding this purported "due diligence," that Walgreens "failed to conduct any meaningful investigation or analysis to ensure that the massive amounts of commonly abused, highly addictive controlled substances being ordered by these pharmacies were not being diverted into other than legitimate channels." The DEA noted that "[Walgreens] has been unable to provide any files related to any effort to adequately verify the legitimacy of any particular order it shipped to its customer stores."

201. These failures were not limited to the specific Florida pharmacies and distribution center described above; instead, they reflect systemic failures of Walgreens's SOM system that impacted its distribution in the City as well. Walgreens admits that the SOM systems and procedures at all of its DCs were the same, including those at the facilities that continued shipping opioids into the City. Accordingly, it is not surprising that, in February 2013, the DEA issued similar Subpoenas and Warrant of Inspection on the Perrysburg DC in Ohio to those issued to the Jupiter DC in Florida. Walgreens employees made plans in preparation for the Perrysburg DC being "shut down" by the DEA, like the Jupiter DC. Within weeks of receiving the six subpoenas and warrant, Walgreens decided to "discontinue distribution of controlled substances from the Perrysburg facility" in order to "eliminate any immediate need for further DEA administrative action" regarding the Perrysburg facility.

202. Further, after the DEA began its investigation, Walgreens held meetings with and informed the DEA that it was implementing "new changes" to "enhance" its SOM program. Internal documents reveal that Walgreens improved its SOM program only "in an effort to convince the DEA that the proposed penalty is excessive."

203. Even so, by November 2012, the program still did not halt the orders for due diligence evaluation or report the orders as suspicious. Further, at that time, the program began to automatically reduce orders that violated ceiling thresholds.

204. There also is no evidence that these flagged or cut orders were reported as suspicious to the regulatory authorities.

205. As a result of the DEA investigation, Walgreens formed the "Rx Integrity Team" in 2012, purportedly to make sure that those types of failures did not continue. However, the group's true role was protecting Walgreens's Distribution Centers and stores from losing their DEA licenses. The effort was only for show. Walgreens never provided the Rx Integrity group the resources needed to achieve due diligence on the large number of orders identified by Walgreen's SOM program for the company's 5,000 plus stores.

206. In December 2012, the further enhanced SOM system flagged "14,000 items that the stores ordered across the chain that would have to be investigated" before they could be shipped. Walgreens admitted that yet again it did not have sufficient resources to timely review these orders. Walgreens noted that "[t]he DEA would view this as further failures of our internal processes, which could potentially result in additional pharmacies and distribution centers being subjected to regulatory actions and ultimately prohibited from handling controlled substances." At the time these 14,000 orders were flagged Walgreens Rx Integrity Team was comprised of fewer than five people. Even at its height, Rx Integrity had only eleven employees. Instead of sufficiently staffing the SOM program, Walgreens recognized it had the ability to control its due diligence workload by increasing the stores' ceiling levels, and thereby reducing the number of orders that would hit that ceiling and result in a flag.

207. As described below, Walgreens admits to failures in its suspicious order monitoring prior to 2012. Comparing the 2013 SOM system to the previous system, one of Walgreens's Pharmaceutical Integrity Managers in August 2013 explained:

> The Controlled Substances Order Monitoring system now in place sets limits for each item based on the chain average for that item for stores of similar size. If a particular store fills more of this item than normal and needs additional product we would need to document the reason and increase via a CSO Override .... The purpose for this is to ensure we have performed adequate review before sending in additional inventory.
>
> **The previous system would continue to send additional product to the store without limit or review which made possible the runaway growth of dispensing of products like Oxycodone, that played a roll [sic] in the DEAs investigation of Walgreens**.

208. Yet, even in 2013, orders being flagged as suspicious for review before shipment were "a week old" before they made it to the review team, often "ha[d] already been shipped," and were not being reported.

209. Walgreens never equipped its distribution operations to properly monitor for, report, and halt suspicious orders, or otherwise effectively prevent diversion. When it became clear Walgreens would need to devote significant resources to achieve compliance, Walgreens chose instead to cease controlled substance distribution all together. Walgreens stated that "while the financial impact of no longer . . . [self distributing] from the Walgreens DCs was taken into consideration, there is a greater risk to the company in fines and loss of licenses if we continue to sell these items in our warehouses."

210. Indeed, with respect to Walgreens's suspicious order monitoring system for its wholesale distribution, the MDL Court has denied a motion for summary judgment contesting the evidence regarding the inadequacy of its SOM system in that litigation. *See* Order Denying Walgreen's Motion for Summary Judgment, MDL No. 2804, Doc. 2569 (N.D. Ohio Sept. 4, 2019).

v. Walgreens Failed to Put in Place Adequate Polices to Guard Against Diversion at the Pharmacy Level

211. Although Walgreens purported to have in place "Good Faith Dispensing" ("GFD") Policies for many years, it failed to meaningfully apply policies and procedures, or to train employees in its retail pharmacies on identifying and reporting potential diversion.

212. Despite knowing that prescribers could contribute to diversion, and having a separate and corresponding duty with respect to filling prescriptions, from at least 2006 through 2012, Walgreens's dispensing policies, which it titled "Good Faith Dispensing", or "GFD", explicitly instructed pharmacists who "receive[] a questionable prescription" or otherwise were "unable to dispense a prescription in good faith" to "contact the prescriber" and, if "confirm[ed]" as "valid" by the prescriber, to then "process the prescription as normal." Further, though Walgreens's policies listed a handful of "questionable circumstances," such as "increased frequency of prescriptions for the same or similar controlled drugs by one prescriber[,] for large numbers of patients [,] for quantities beyond those normally prescribed," it is unclear what, if any, resources Walgreens made available to its pharmacists for checking these vague criteria, which, in any event, became meaningless if a prescriber "confirm[ed]" the prescription as "valid," by calling the prescriber. For example, in 2010 when a pharmacy manager expressed concern about significant numbers of opioid prescriptions from pain clinics, and being help responsible for "excessive c2 rx dispensing," her district supervisor instructed her "not [to] refuse script for large quantities" but simply to "call the MD's, document it on the hard copy[,] and that is all that is needed to protect your license." Despite internally recognizing that "a prescriber of a controlled substance prescription [may be] involved in diversion", Walgreens's GFD policies continued to endorse calling the doctor as a greenlight to any "questionable" prescription.

213. In 2012, Walgreens finally removed the "process the prescription as normal" language from its formal GFD policies, admitting that under the law "it is not enough to get confirmation that the prescriber wrote the prescription." However, Walgreens still failed to ensure it complied with its duties.

214. Walgreens failed to adequately train its pharmacists and pharmacy technicians on how to prevent diversion, including what measures and/or actions to take when a prescription is identified as phony, false, forged, or otherwise illegal, or when other suspicious circumstances are present, and failed to provide them the means of doing so. To be clear, this required no inquiry into whether an opioid prescription was the proper treatment for a particular patient; instead, as a registrant, Walgreens was obligated, and failed, to implement policies and procedures at a corporate level to identify and address signs of diversion.

215. Indeed, during the course of a 2009 DEA investigation into Walgreens dispensing noncompliance, Walgreens internally noted that it currently had "no training" for employees dispensing controlled substances. Meanwhile, Walgreens corporate officers turned a blind eye to these abuses. In fact, a Walgreens corporate attorney suggested, in reviewing the legitimacy of prescriptions coming from Florida, that "if these are legitimate indicators of inappropriate prescriptions perhaps we should consider not documenting our own potential noncompliance," underscoring Walgreens's attitude that profit outweighed compliance with the law or protecting public health.

216. Ultimately, in 2011, Walgreens and the DEA entered a Memorandum of Agreement regarding all "Walgreens . . . pharmacy locations registered with the DEA to dispense controlled substances," requiring Walgreens to implement significant nationwide controls lacking in its operations. Walgreen Co. was required to create a nationwide "compliance program to detect and

prevent diversion of controlled substances ***as required by the … (CSA) and applicable DEA regulations***." Pursuant to the MOA, the "program shall include procedures to identify the common signs associated with the diversion of controlled substances including but not limited to, doctor-shopping and requests for early refills" as well as "routine and periodic training of all Walgreens walk-in, retail pharmacy employees responsible for dispensing controlled substances on the elements of the compliance program and their responsibilities under the CSA." Further, Walgreens was required to "implement and maintain policies and procedures to ensure that prescriptions for controlled substances are only dispensed to authorized individuals pursuant to federal and state law and regulations."

217. Walgreens would also make more promises in a 2013 Memorandum with the DEA, described further below, related to failures to that lead to the ISOs described above.

218. Even after development and a relaunch of its GFD policy in response to settlements with the DEA, however, Denman Murray, Director of Rx Supply Chain Retail, stated in an MDL deposition that, "traditionally, we've always treated a controlled substance like any other, [a] widget's a widget to the system."

219. Further, after the June 2012 GFD "relaunch" in April 2014, a Walgreens "RxIntegrity" presentation focused on Walgreens "Market 25," but also assessing "average market" trends, reported that "pharmacists [were] not being too strict with GFD, nor [were] they losing volume."[26]

220. As with distribution, Walgreens failed to allocate appropriate resources to dispensing compliance and supervision. Walgreens has approximately 26,000 pharmacists, each

[26] Market 25 consisted of Indiana, Kentucky, and West Virginia. Similar results reported for Market 3, Florida.

of whom may receive as many as 400-500 prescriptions a day. In 2013, however, Walgreens internally reported that its District Managers and Pharmacy Supervisors were "challenged to get into the stores" and in a 90-day period, more than a thousand stores did not receive a visit from the managers or supervisors. These supervisory personnel were assigned a "high number of stores" and their time was consumed with "people processes, business planning, market and district meetings," such that supervision in store was being handled informally by "community leaders" who have "limited formal authority."

221. Even where Walgreens's policies recognized red flags, Walgreens failed to provide its pharmacists with effective tools for assessing them. For example, Walgreens's policies and internal documents acknowledged that distance between the patient, pharmacists, and/or prescriber constituted a red flag, however, Walgreens did not even begin piloting an automated process for flagging such distances through common and long available technological solutions until the Spring of 2021.

222. Walgreens knew its much touted good faith dispensing, or "GFD," policies were ineffective, and, in 2013, it launched a "Target Drug GFD" program to purportedly "put teeth around GFD for high risk products." The policies required pharmacists to perform extra checks on red flags and to complete TD GFD checklists when presented with certain opioid prescriptions. However, the TDGFD procedures were largely window dressing. Walgreens deliberately omitted hydrocodone from its TDGFD process, despite knowing in 2013 that HCPs were the most abused of all prescription opioids, and in 2019 was still considering whether to add hydrocodone, even though it had been a Schedule II opioid since 2014. Walgreens further failed to make the TDGFD checklist an electronic form until 2020, despite knowing that doing so would make compliance and supervision more effective. A review of Walgreens's TDGFD forms in certain jurisdictions

reveals Walgreens failed to even complete a TDGFD form for as many as half of the prescriptions for which Walgreens's own policies stated such a form was required.

223. A Walgreens internal audit performed after the 2013 DEA settlement confirms that Walgreens's supervision and compliance failures continued. Among other failings, the audit team noted no formal monitoring program existed to confirm that pharmacies across the chain are complying with controlled substance documentation and retention requirements, no monitoring outside of the deficient "store walk program" existed to monitor target drug good faith dispensing requirements and no corporate reporting was being generated, and employees were failing to timely complete Good Faith Dispensing training, such that, at the time of the audit, over 35,000 employees had not completed their required training for that year. Management's response largely was to seek to incorporate additional compliance measures into the store walk procedure. However, documents from 2016 regarding monthly store compliance walks indicate that during the monthly "Compliance Walks" to "verify compliance … [with] regulatory requirements in… pharmacy areas," substantially no dispensing compliance supervision occurred, outside of ensuring the pharmacy was verifying the patient's address on five sample prescription fills.

224. Unsurprisingly, compliance with GFD and TD GFD has been poor. For example, in 2014 Walgreens discovered a pharmacist who failed to follow GFD for five to six months without being discovered by supervisors. In 2014, Rx Integrity noted dozens of stores dispensing opioids without performing the required checks. In certain cases, the pharmacists were unaware of the GFD procedures or had been told by supervisors to disregard them.

225. In 2015, Walgreens performed a "business continuity" audit of a random sample of approximately 2,400 pharmacies to determine whether Walgreens was "compliant with the policies/procedures put in place" regarding dispensing pursuant to Walgreens's agreement with

the DEA. As the audit progressed, Walgreens internally noted "put your seatbelts on" because the audits were "not going great" and they would need to implement a "mitigation plan … to satisfy the MOA" for the non-compliance revealed by the audit. In Walgreens's own words, "Results were unfavorable." Fewer than 60% of stores were complying with TD GFD with respect to filled prescriptions, 1,160 stores did not have a single refused prescription, and an additional 1,182 stores had refused fewer than 25 prescriptions total in a nine-month period. Only 63 out of 2,400 pharmacies had refused 26 or more prescriptions during that same nine months in 2015.

226. Walgreens's determination to bury evidence of noncompliance in the service of profit goals has continued. When a Walgreens consultant interviewed Walgreens pharmacy employees, they drafted a report finding that employees "sometimes skirted or completely ignored" proper procedures to meet corporate metrics and committed "errors resulting from stress." The consultants reported that they "heard multiple reports of improper behavior" that was "largely attributed to the desire" to meet a corporate metric known as "promise time," which ensures that patients get prescriptions filled within a set amount of time. Upon reviewing a draft of the report, senior leaders at Walgreens directed the consultants to remove some of the damaging findings, which the consultant company ultimately did, even though the consultant's employees stated requests to remove information from slides conflicted with their business ethics. At around this same time, Walgreens award the consultant company a $1.5 billion contract.

vi. Walgreens Assumed Greater Responsibility for Controlling Against Diversion by Discouraging Outside Vendors from Exercising Their Own Oversight

227. The "Big Three" wholesalers, Cardinal, McKesson, and AmerisourceBergen, gave deferential treatment to chain pharmacies. An internal Cardinal document for example, stresses that "certain chain pharmacies refuse to allow any sort of administrative inspection by Cardinal or

to make certifications" and that large, national chains can "take their billions upon billions of dollars in business to any wholesaler in the country."

228. Thus, for example, in 2008, Cardinal prepared talking points for a NACDS Conference about its planned retail chain SOM program, making it clear that the program would "minimize the disruption" to retail chains and that they would "work together" with the pharmacies "to ensure that our Suspicious Order Monitoring program for retail chains does not interrupt" business. Cardinal also provided warnings to chain pharmacies, including Walgreens, that they were approaching thresholds so that the chains could avoid triggering SOM reporting and adjust ordering patterns by, for example, delaying orders or, more often, obtaining a threshold increase. Such "early warnings" were so helpful to Walgreens that as of 2012 Walgreens adopted the concept for its own SOM system for self-distribution, noting internally that by "flagging the stores at 75%," it could "avoid cutting/reducing orders and subsequently not have to report a SOM to the DEA."

229. Preferential treatment of Walgreens ultimately was not enough for Cardinal to keep Walgreens's business, however. In 2013, Walgreens entered a ten-year agreement with AmerisourceBergen Drug Company. The shift to AmerisourceBergen as its exclusive supplier prompted Cardinal to complain: "we bailed you guys out when you had your [DEA] issues."

230. By 2017, Walgreens accounted for 30% of AmerisourceBergen's revenue.[27] AmerisourceBergen was similarly deferential, allowing Walgreens to "police their own orders

[27] As a part of its distribution agreement, Walgreens gained purchase rights to AmerisourceBergen equity, allowing it to further participate in the prescription opioid shipment boom in America. Walgreens subsequently exercised these purchase rights, ultimately owning approximately 26% of AmerisourceBergen. As part of the transaction, Walgreens has the ability to nominate up to two members of the Board of Directors of AmerisourceBergen. Currently, Walgreen's Co-Chief Operating Officer sits on the AmerisourceBergen Board of Directors.

and block any order to [AmerisourceBergen ("ABC")] that would exceed ABC's threshold thus triggering a suspicious order being sent to DEA from ABC. Additionally, when AmerisourceBergen received orders from Walgreens "outside the expected usage," Walgreens and AmerisourceBergen met to discuss adjusting thresholds or using "soft blocking." Contrary to DEA guidance and its own stated policy, AmerisourceBergen also shared the threshold limits set by its "order monitoring program" with Walgreens, and also provided Walgreens with weekly SOM statistics. AmerisourceBergen generally would not take action on Walgreens orders that exceeded its thresholds without first talking to Walgreens.

231. Walgreens also owns 26% of AmerisourceBergen's stock. In 2018, after a coalition of AmerisourceBergen shareholders sought greater transparency from its Board related to the "financial and reputational risks associated with the opioid crisis," Walgreens, together with other insiders, reportedly leveraged this position to defeat the proposal, which enjoyed majority support among the independent shareholders.

vii. Walgreens Failed to Maintain Effective Controls Against Diversion in the City

232. As described above and further below, as both a distributor and a dispenser, Walgreens ignored indicia of diversion in Florida and the City.

233. In the City, as a distributor, Walgreens shipped more than ***45.3 million*** dosage units into Sarasota County from 2006-2014. In total, at the pharmacy level, Walgreens purchased more than ***32.4 million*** dosage units of opioids shipped to stores in the City from 2006 to 2014. This included the highest-buying store within Sarasota County, which alone purchased more than 7 million dosage units of opioids, according to public information, during that time.

234. In addition, Walgreens, upon information and belief, also distributed and dispensed substantial quantities of prescription opioids in the surrounding area, and these drugs were diverted

from the surrounding area into the City. Walmart failed to take meaningful action to stop this diversion despite its knowledge of it, and it contributed substantially to the opioid epidemic in Florida.

235. Walgreens violated the standard of care for a distributor by failing to: (a) control the supply chain; (b) prevent diversion; (c) report suspicious orders; and (d) halt shipments of opioids in quantities it knew or should have known could not be justified and signaled potential diversion.

236. The volume of opioids Walgreens shipped into, and dispensed from locations in, the City was so high as to raise a red flag that not all of the prescriptions being ordered could be for legitimate medical uses.

237. Yet, upon information and belief, Walgreens failed to report suspicious orders of opioids in the City between 2007 and 2014**.** Instead, Walgreens funneled far more opioids into Florida and the City than could have been expected to serve legitimate medical use, and ignored other indicia of suspicious orders. This information, along with the information known only to distributors such as Walgreens (especially with its pharmacy dispensing data), would have alerted Walgreens to potential diversion of opioids.

238. Meanwhile, almost every Walgreens in the City bought more than a million dosage units of opioids from 2006-2014.

239. Walgreens also developed and maintained highly advanced data collection and analytical systems. These sophisticated software systems monitor the inventory and ordering needs of customers in real-time and depicted the exact amounts of pills, pill type, and anticipated order threshold for its own stores.

240. Through this proprietary data, Walgreens had direct knowledge of patterns and instances of improper distribution, prescribing, and use of prescription opioids in Florida, including in the City. It used this data to evaluate its own sales activities and workforce. Walgreens also was in possession of extensive data regarding individual doctors' prescribing and dispensing to its customers, the percentage of a prescriber's prescriptions that were controlled substances, individual prescription activity across all Walgreens stores, and the percentages of prescriptions purchased in cash. Such data are a valuable resource that Walgreens could have used to help stop diversion, but it did not.

241. Walgreens, by virtue of its data analytics, was actually aware at a corporate level of indicia of diversion, such as (1) individuals traveling long distances to fill prescriptions; (2) prescriptions for drug "cocktails," known for their abuse potential, such as oxycodone and Xanax; (3) individuals who arrived together with identical or nearly identical prescriptions; (4) high percentage of cash purchases; and (5) doctors prescribing outside the scope of their usual practice or geographic area. However, Walgreens failed to effectively make the data demonstrating these obvious flags available to its pharmacists and failed to properly address the red flag dispensing patterns.

242. Walgreens also failed to adequately use data available to it to identify doctors who were writing suspicious numbers of prescriptions and/or prescriptions of suspicious amounts or doses of opioids, or to adequately use data available to it to prevent the filling of prescriptions that were illegally diverted or otherwise contributed to the opioid crisis. While Walgreens periodically implemented programs that would identify the most suspicious prescribers, it failed to make this data readily available to its pharmacists, and either terminated or failed to act on them at the corporate level.

243. Upon information and belief, Walgreens failed to adequately analyze and address its opioid sales relative to: (a) the number of opioid prescriptions filled by its pharmacies relative to the population of the pharmacy's community; (b) the increase in opioid sales relative to past years; and (c) the number of opioid prescriptions filled relative to other drugs.

244. At the store level, Walgreens did not make any controlled substance metrics available to pharmacists for specific prescribers. Further, despite the fact that at the corporate level Walgreens utilized many tools, including IMS, for descriptive statistics around prescriber patterns, Walgreens was not aware of any consistent reports written using that data. Instead, when a pharmacist or Walgreens team member had a concern about a particular prescriber ad hoc prescriber profiles were pulled. However, these reports were difficult to interpret so corporate would have to assist with the analysis and interpretation of the reports.

245. Walgreens failed to adequately analyze and address its opioid sales relative to: (a) the number of opioid prescriptions filled by its pharmacies relative to the population of the pharmacy's community; (b) the increase in opioid sales relative to past years; and (c) the number of opioid prescriptions filled relative to other drugs. For example, Walgreens ran reports known as "GFD Opportunities reports," generated from data on its individual pharmacies and pharmacists. A "GFD Opportunities" tool included information such as "Cash rank, Oxycodone IR rank, "target" drug quantity rank, and target drug rate rank. With the information available to it, Walgreens thus knew which pharmacists filled more controlled substances prescriptions that others, however, Walgreens failed to meaningfully act to curtail red flag dispensing.

246. Upon information and belief, based on other enforcement actions against the company, Walgreens also failed to conduct adequately analyze and address its opioid sales to

identify patterns regarding prescriptions that should not have been filled and to create policies accordingly, or if it conducted such reviews, it failed to take any meaningful action as a result.

247. Discovery will reveal that Walgreens knew or should have known that its pharmacies in Florida, and the surrounding area, were (a) filling multiple prescriptions to the same patient using the same doctor; (b) filling multiple prescriptions by the same patient using different doctors; (c) filling prescriptions of unusual size and frequency for the same patient; (d) filling prescriptions of unusual size and frequency from out-of-state patients; (e) filling an unusual or disproportionate number of prescriptions paid for in cash (f) filling prescriptions paired with other drugs frequently abused with opioids, like benzodiazepines, or prescription "cocktails"; (g) filling prescriptions in volumes, doses, or combinations that suggested that the prescriptions were likely being diverted or were not issued for a legitimate medical purpose; and (h) filling prescriptions for patients and doctors in combinations that were indicative of diversion and abuse. Also, upon information and belief, the volumes of opioids distributed to and dispensed by these pharmacies were disproportionate to non-controlled drugs and other products sold by these pharmacies, and disproportionate to the sales of opioids in similarly sized pharmacy markets. Walgreens had the ability, and the obligation, to look for these red flags on a patient, prescriber, and store level, and to refuse to fill and to report prescriptions that suggested potential diversion.

248. Walgreens admits its role in the opioid epidemic, stating it has the "ability – and [] critical responsibility – to fight the opioid crisis" as the "nation's largest pharmacy chain" in a time when "[a]ddiction to prescription painkillers, heroin, and other opioids has surged, with opioid overdoses quadrupling in this decade" and "drug overdose deaths – the majority from prescription and illicit opioids" resulting in "more fatalities than from motor vehicle crashes and gun homicides

combined." Walgreens also admits the "opioid crisis" is caused by "misuse, abuse and addiction" that result from the "flow of opioids that fuel the epidemic."

b. Publix

249. In both its capacity as a distributor and as a dispenser of controlled substances, Publix failed to implement effective policies and practices to prevent diversion of opioids in and around Plaintiff's community.

250. During the time period relevant to Plaintiff's claims, Publix acted as both a distributor of controlled substances to its own pharmacies and a retailer dispensing controlled substances. Publix warehoused and self-distributed controlled substances to its stores, including opioids, from a warehouse devoted to pharmacy products in Orlando, Florida ("Orlando Warehouse").

i. Publix Failed to Maintain Effective Controls Against Diversion at the Wholesale Level

251. Publix failed to implement an effective suspicious order monitoring program.

252. Publix distributed and continues to distribute controlled substances to its own Publix stores. Publix distributed to the City through its Orlando Warehouse, a DEA registrant. As of 2012, the Orlando Warehouse shipped to all Publix pharmacies two to three times per week.

253. Publix supplemented its own self-distribution of opioids with distribution by industry players, including McKesson and AmerisourceBergen. Even if Publix's distribution center reduced an order to a smaller number of bottles, nothing prevented a Publix pharmacy from making up the difference by ordering opioids from third party distributor, such as McKesson and AmerisourceBergen. Not only could Publix pharmacies place another order with these outside vendors to make up the difference, they could have orders fulfilled by both Publix and a third-party distributor at the same time.

254. Ultimately, Publix's distribution system made it nearly impossible for any order to be identified, much less reported, as suspicious. Publix placed orders of controlled substances from manufacturers and distributors who prioritized sales goals over suspicious order monitoring duties. Publix also gave significant latitude to its employees to manipulate order size and thresholds. As a result of the company's policies and procedures, Publix did not—and indeed, could not—identify what was unusual.

255. In 2015, a Teva employee, Joe Tomkiewicz, identified a potentially suspicious order by Publix through Anda, Inc., which was then one of Teva's wholesaler customers. Tomkiewicz identified "serious red flags" with regard to the Publix order, including:

> 1. This is high-strength oxycodone ultimately going to Florida, a well-established hot spot for oxycodone abuse in the U.S.
> 2. The total quantities in the Publix forecast put them significantly above their peers as far as size and class of trade are concerned.
> 3. The breakdown by strength, with an emphasis on 40mg does not appear to be normal for a retail pharmacy. I would expect the breakdown to be closer to that of Thrifty White, where the emphasis is on lower strengths.

256. Tomkiewicz was ultimately pressured by Teva's Director of National Accounts, Jocelyn Baker, to overlook the "serious red flags" in Publix's order and permit the order to process. Ms. Baker highlighted Publix's importance as customer as the reason, "Publix is an established customer who sells some of our other control[led substances]," and "[t]his was not presented to them in advance and may put this award at risk."

257. Distributor McKesson provided Publix with notification of stores hitting McKesson's thresholds and regularly granted threshold increases without conducting any due diligence.

258. For example, in 2009, McKesson alerted Publix employees Chris Hewell, Paul Hines, and Ivonne Leon, that several of its accounts were over 80% of their authorized threshold, with "[s]everal stores already at 100%." Publix employee Chris Hewell, Manager of Procurement,

responded, requesting "amnesty" from the ordering threshold program, thus permitting Publix to exceed the standard 80% threshold for ordering Oxycodone. While Ms. Martindale's initial internal response was, "I'm pretty sure this isn't something we can do," McKesson ultimately granted Publix a temporary 2000 dosage unit increase "across the board."

259. Publix allowed its individual stores to order from third party distributors without any, or limited, restrictions and, upon information and belief, did not sufficiently take those orders into account in Publix's self-distribution SOM system, negating any constraints from Publix's internal controls.

260. For example, in 2013, Lucy Bard, National Account Manager at Purdue, reported to her superiors at Purdue that after calling on several Publix pharmacies in St. Petersburg, Florida, "[n]ot one pharmacist has experience a push back with ordering OxyContin or maximizing their quantities per McKesson/DEA regulations."

ii. Publix Failed to Maintain Effective Controls Against Diversion in the City

261. In the City, Publix violated the standard of care for a distributor by failing to: (a) control the supply chain; (b) prevent diversion; (c) report suspicious orders; and (d) halt shipments of opioids in quantities it knew or should have known could not be justified and signaled potential diversion.

262. The Publix pharmacies in the City purchased and dispensed more than ***8.9 million*** dosage units of opioids from 2006 to 2014, the years for which ARCOS data is available. The volume of opioids it shipped into, and dispensed from locations in, the City is so high as to raise a red flag that not all of the prescriptions being ordered could be for legitimate medical uses.

263. As a vertically integrated distributor and dispenser of prescription opioids, Publix knew or should have known that an excessive volume of pills was being sold into Florida and the

City and ultimately, onto its streets. Publix's activities as a distributor and a seller or dispenser of opioids are inextricably linked.

264. The sheer volume of prescription opioids distributed to and dispensed by Publix pharmacies in and around the City, with a population of about 51,917 residents in 2010, is indicative of potential diversion and required appropriate due diligence.

265. Publix funneled far more opioids into Florida and the City, and out of its pharmacy doors, than could have been expected to serve legitimate medical use, and ignored other indicia of diversion, including but not limited to suspicious orders.

266. It cannot be disputed that Publix was aware of the suspicious orders that flowed from its distribution facilities into its own stores. Publix simply refused to identify, investigate, and report suspicious orders even though Publix knew, or should have been fully aware, that opioids it distributed and sold were likely to be diverted. Conversely, Publix failed to report suspicious orders, failed to meaningfully investigate or reject suspicious orders, and failed to prevent diversion, or otherwise control the supply of opioids flowing into Florida and the City.

267. Upon information and belief, Publix failed to analyze: (a) the number of opioid prescriptions filled by its pharmacies relative to the population of the pharmacy's community; (b) the increase in opioid sales relative to past years; and (c) the number of opioid prescriptions filled relative to other drugs.

268. Publix was, or should have been, fully aware that the opioids being distributed and dispensed by it were likely to be diverted. Yet it did not take meaningful action to investigate or to ensure that it was complying with its duties and obligations with regard to controlled substances, including its responsibility to report suspicious orders and not to ship such orders unless and until due diligence allayed the suspicion.

269. Given Publix's retail pharmacy operations, in addition to its role as a wholesale distributor, Publix knew, or reasonably should have known, about the disproportionate flow of opioids into Florida and the City and the operation of "pill mills" that generated opioid prescriptions that, by their quantity or nature, were red flags for, if not direct evidence of, illicit supply and diversion.

270. In addition, and upon information and belief, Publix knew, or deliberately turned a blind eye to, its pharmacies' role in diversion of dangerous drugs. At the pharmacy level, discovery will reveal that Publix knew, or should have known, that its pharmacies in Florida were (a) filling multiple prescriptions to the same patient using the same doctor; (b) filling multiple prescriptions by the same patient using different doctors; (c) filling prescriptions of unusual size and frequency for the same patient; (d) filling prescriptions of unusual size and frequency from out-of-state patients; (e) filling an unusual or disproportionate number of prescriptions paid for in cash; (f) filling prescriptions paired with other drugs frequently abused with opioids, like benzodiazepines, or prescription "cocktails"; (g) filling prescriptions in volumes, doses, or combinations that suggested that the prescriptions were likely being diverted or were not issued for a legitimate medical purpose; and (h) filling prescriptions for patients and doctors in combinations that were indicative of diversion and abuse. Publix had the ability, and the obligation, to look for these red flags on a patient, prescriber, and store level, and to refuse to fill and to report prescriptions that suggested potential diversion.

271. Because of its vertically integrated structure, Publix has access to complete information regarding red flags of diversion across its pharmacies in and around the City, but Publix chose not to utilize this information and failed to effectively prevent diversion.

iii. Publix Failed to Implement Effective Policies and Procedures to Guard Against Diversion from its Retail Stores

272. At all times relevant herein, Publix pharmacies sold controlled substances, including FDA Schedule II and FDA Schedule III controlled substances otherwise known as opiate narcotics or opioids.

273. "Publix Supermarkets, Inc," not any individual Publix store, is the DEA registrant for each of Publix's pharmacies across the country.

274. As described above, Publix pharmacies ordered and were supplied opioids from a combination of outside vendors and Publix's own Orlando Warehouse.

275. Upon information and belief, Publix lacked meaningful policies and procedures to guide its pharmacy staff in maintaining effective controls against diversion.

276. Publix's conduct, and the volume it dispensed in the City thereafter indicates that, to the extent any policies existed, those policies were not consistently and reliably applied. In addition, as discussed further below, Publix pressured pharmacists to put profits ahead of safety.

277. Upon information and belief, Publix failed to use data held at the corporate level to assist pharmacists in evaluating red flags of diversion.

iv. Publix Failed to Guard Against Diversion in Dispensing to the City

278. Upon information and belief, Publix pharmacies routinely have dispensed opioids in violation of the Controlled Substances Act and accompanying regulations. Such conduct was a result of Publix's lack of robust policies and procedures regarding dispensing controlled substances as well as Publix's focus on profitability over its legal obligations and public safety.

279. As a sophisticated chain pharmacy, Publix had the ability to analyze data relating to drug utilization and prescribing patterns across multiple retail stores in diverse geographic locations. Its own data would have allowed Publix to observe patterns or instances of dispensing

that are potentially suspicious, of oversupply in particular stores or geographic areas, or of prescribers or facilities that seem to engage in improper or illegitimate prescribing.[28]

280. Publix did not use data available to it to effectively comply with its legal obligations to prevent diversion and ensure only legal prescriptions were being filled at its pharmacies.

281. Upon information and belief, Publix provided its pharmacists no or limited visibility into the data it collected, thereby depriving them of an invaluable resource when evaluating prescriptions.

282. Publix did not make it possible, much less easy, for pharmacists to share information about red flags, suspicious prescribers, and suspicious patients.

283. To the extent Publix did provide its pharmacists with any visibility into the data it collected, Publix deprived its pharmacists of the ability to meaningfully review and apply this data by making such significant demands on its pharmacists that it effectively prevented them from properly evaluating potential red flags, suspicious prescribers, and suspicious patients.

284. For example, a 2022 job posting for a "Pharmacist – 30-hour Floater" in an Orlando, Florida Publix store lists an overwhelming list of skills needed for an applicant:

[28] *See, e.g.*, *Holiday CVS, L.L.C., d/b/a CVS/Pharmacy Nos. 219 and 5195*, 77 Fed. Reg. 62,315 (Dep't of Justice Oct. 12, 2012) (decision and order) (DEA expert witness examined dispensing records alone to identify inappropriately dispensed medications).

- provide dedication to each pharmacies success, by executing strategy, motivating and inspiring staff as the pharmacist-on-duty
- set priorities to maximize contribution, executing daily tasks, supporting the team and building rapport with both customers and associates
- provide best-in-class pharmacy service to patients, empower your staff in providing value and service through counseling, building personalized relationships, promoting customer loyalty, offering pharmacist led clinical services to improve health and wellness and preventative care through services available at Publix
- inspire each team you work with to do the right thing, gaining buy in, and empowering the team to be accountable
- provide enthusiasm for all new pharmacy initiatives at your assigned location
- manage team performance, such as prescription promised time, by assigning tasks to ensure complex operational activities are met in a timely and efficient manner in the absence of the pharmacist-in-charge
- use best practices to make sound business decisions while covering as the pharmacist-on-duty
- be regarded as an expert on the pharmacy technology system and how it is used for both routine and complex prescription processing
- mentor others on Publix pharmacy best practices to maximize sales, minimize shrink while meeting customers' needs, using programs such as auto refill and Sync Your Refills
- proactively advance pharmacy clinical initiatives including Medication Therapy Management (MTM), pharmacist point-of-care testing, immunizations, and diabetes management
- maintain a flexible work-week schedule in order to meet the needs of our customers, and
- assist in all other duties as assigned.

285. The laundry list of responsibilities included in the "Pharmacist – 30-hour Floater" posting repeatedly highlights a pharmacist's role in pharmacy success, maximizing sales, meeting customers' needs, and gaining customer loyalty, still, the responsibilities list makes no mention of a pharmacists' role in identifying and evaluating potential red flags, suspicious prescribers, and suspicious patients.

286. In addition, Publix placed strict emphasis on its pharmacists filling prescriptions as quickly as possible while Publix simultaneously limited resources available to assist pharmacists.

287. While the above job description details that the pharmacist must inspire staff and team work, in reality many Publix pharmacists lament publicly that Publix pharmacists often work without the aid of a pharmacy technician or other staff. When pharmacy technicians are unavailable or pulled away to other areas in the supermarket, Publix pharmacists are forced to

work alone, and to act as both pharmacist and technician. This lack of resources or aid impairs a pharmacist's ability to address patient safety and patient care, including his or her ability evaluate potential red flags, suspicious prescribers, and suspicious patients.

288. The problem of illegal dispensing caused by Publix's focus on quickly filling prescriptions and increasing the number of prescriptions dispensed was exacerbated by Publix's inadequate pharmacy staffing. This greatly cut into the ability of the pharmacist to evaluate each prescription carefully and in accordance with the law.[29]

289. In addition, the job posting for "Pharmacist – 30-hour Floater" position states the position is eligible for a "Retail bonus" benefit which is paid quarterly, and is "based on sales and profits that are calculated at the end of each inventory period."

290. Publix's compensation structure presents a conflict of interest for pharmacists on at least one front as it incentivizes pharmacists to fill as many prescriptions as possible to increase the store profit metric. In this structure, a pharmacist would necessarily receive a higher bonus for filling illegitimate prescriptions (by increasing store profits). On the other hand, rejecting illegitimate prescriptions would decrease overall sales and profits, and decrease the final bonus amount a pharmacist could receive.

c. Walmart

291. During most of the time period relevant to Plaintiff's claims, Walmart acted as both a distributor of controlled substances to its own Walmart pharmacies and a retailer dispensing controlled substances at Walmart pharmacies and Sam's Club pharmacies. While operating under

[29] Some states have tried to outlaw pharmacists from working alone. California, for example, passed a law saying no pharmacist could be required to work alone. Regrettably, however, it has been largely ignored since taking effect in 2019, according to leaders of a pharmacists' union. *See* Gabler, Ellen, *How Chaos at Chain Pharmacies is Putting Patients at Risk*, THE NEW YORK TIMES (Jan. 31, 2020), https://www.nytimes.com/2020/01/31/health/pharmacists-medication-errors.html.

different brand names, both Walmart and Sam's Club pharmacies were subject to the same flawed policies, lack of oversight, and inadequate implementation emanating from Walmart's Home Office. In both its capacity as a distributor and as a dispenser of controlled substances, Walmart failed to implement effective policies and practices to prevent diversion of opioids in and around Plaintiff's community. By the time Walmart implemented a system for monitoring suspicious orders or policies allowing corporate blocks of known pill mill doctors, the opioid epidemic had already claimed hundreds of thousands of American lives.

292. Walmart is the largest private employer in the United States, employing over 1.5 million people. But for years, Walmart chose not to assign a single employee to design or operate a system to detect suspicious orders of controlled substances. Despite Walmart's obligations as a distributor of controlled substances, it was not until 2014 that Walmart began to take any meaningful steps toward developing a system for monitoring suspicious orders.

i. Walmart Lacked a Suspicious Order Monitoring System for Most of the Relevant Time Period

293. Walmart operated registered distribution centers to supply its own pharmacies with controlled substances from the early 2000s until 2018.

294. Prior to 2011, Walmart did not have any written policy or procedure in place to monitor orders of controlled substances shipped by its pharmacy distribution centers.

295. In the absence of an established policy or procedure, Walmart relied on its hourly employees and associates filling orders at the distribution centers to subjectively monitor the orders they were filling for anything unusual. These associates were responsible for filling and reviewing several hundred orders a day.

296. Walmart did not provide any guidance or training to its associates as to what constitutes a suspicious order or how to evaluate an order for unusual size, frequency, or pattern. On information and belief, no Walmart employee ever flagged an order as suspicious prior to 2011.

297. Although Walmart did create a procedure for identifying suspicious orders of controlled substances beginning in 2011, this procedure was insufficient to identify suspicious orders of controlled substances. Walmart's program flagged only very large orders of controlled substances. Specifically, it flagged weekly orders for controlled substances of 50 bottles (5,000 dosage units) or more and orders for more than 20 bottles (2,000 dosage units) that were 30% higher than a rolling four-week average for that item. Orders under 2,000 dosage units per week were never flagged, meaning that a pharmacy could order 8,000 dosage units per month without ever being flagged. Moreover, that meant that even if an order was more than 30% greater than the four-week average, it could not draw an alert unless it also was more than 20 bottles.

298. Under this system, an alert did not mean Walmart would report the order to the DEA or halt it pending necessary due diligence. To the contrary, upon information and belief, Walmart *never* reported an order flagged by its monitoring program to the DEA as suspicious. In addition, rather than halting the order, Walmart simply cut the order to the amount of the 50-bottle threshold and shipped it. Walmart never reported cut orders to the DEA. Although the distribution centers sent information regarding flagged orders daily to Walmart's corporate headquarters in Arkansas (the "Home Office"), no system existed for follow-up on flagged orders by employees at the Home Office .

299. In mid-2012, Walmart implemented a "hard limit" on orders of a single opioid product, 30 mg oxycodone ("Oxy 30"). Under this approach, an order for over twenty bottles of

Oxy 30 was automatically reduced to twenty bottles. Walmart would not report these excessive orders of Oxy 30 to the DEA.

300. At the same time, Walmart's distribution center began generating a daily report of all the pharmacies placing orders for over twenty bottles of various oxycodone medications, although Walmart did not place a "hard limit" on any dosage strength or product other than Oxy 30. This report, called the "Over 20 Report" later included other controlled substances as well. Although the report was generated and circulated on a daily basis, Walmart did not have an adequate system in place to review and follow up on these excessive orders beyond investigating for indicators of internal theft, and it did not have a system in place to address stores that repeatedly appeared on the Over 20 Report. Regardless of having been identified on the Over 20 Report, these orders were filled and shipped. Upon information and belief, there is no evidence of any order in fact being held or halted pursuant to this practice.

301. Even if Walmart's distribution center reduced an order to a smaller number of bottles, nothing prevented a Walmart or Sam's Club pharmacy from making up the difference by ordering opioids from an outside distributor, such as McKesson and AmerisourceBergen. Not only could Walmart pharmacies place another order with these outside vendors to make up the difference, they could have orders fulfilled by both Walmart and a third-party distributor at the same time. Even though Walmart had the ability to monitor orders to outside vendors for suspicious orders, it did not, which allowed Walmart pharmacies to exceed the already high thresholds simply by ordering drugs from a third party.

302. Walmart knew that these policies and procedures were insufficient to fulfill its obligations to prevent diversion of controlled substances. For example, in 2013, Walmart acknowledged in an internal presentation that it had not yet designed a compliant system for

suspicious order identification, monitoring, and reporting. It also stated that it was "TBD" when Walmart would develop such a system. In 2014, Walmart acknowledged that it still lacked a compliant monitoring program and that it had "no process in place" to comply with government regulations and that this created the "severe" risk of "financial or reputational impact to the company." At this point, Walmart still had no written policies and procedures required orders of interest to be held and investigated.

303. In 2015, Walmart enhanced its suspicious order monitoring policy by implementing store-specific thresholds. Upon information and belief, it based these thresholds on the standard deviation of a specific pharmacy's order history for each controlled substance. The thresholds also included minimum amounts, below which no orders were flagged under any circumstance, regardless of pattern or frequency.

304. For almost all Walmart pharmacies, this minimum was set at 2,000 dosage units per week (or 8,000 dosage units per month). An order under this minimum threshold would not be flagged regardless of changes in ordering patterns. A pharmacy could, for example, go from ordering 10 dosage units of Oxycodone 10 mg per month to 7,999 per month without any order being flagged or reviewed. Thus, even Walmart's "enhanced" order monitoring program failed to provide effective controls against diversion.

ii. Walmart Failed to Guard Against Diversion in Distributing into the City

305. According to data from the ARCOS database, between 2006 and 2014, Walmart ordered more than ***3.59 million*** dosage units of oxycodone and hydrocodone for four Walmart and Sam's Club pharmacies in the City. In total, Walmart distributed more than ***7.7 million*** dosage units of oxycodone and hydrocodone into Sarasota County. The volume of opioids Walmart

brought into the City and surrounding County was so high as to raise a red flag that not all of the prescriptions being ordered could be for legitimate medical uses.

306. Yet, upon information and belief, Walmart did not report suspicious orders in the City between 2007 and 2014. Instead, Walmart funneled far more opioids into Florida and the City than could have been expected to serve legitimate medical use, and ignored other red flags of suspicious orders. This information, along with the information known only to distributors such as Walmart (especially with its pharmacy dispensing data), would have alerted Walmart to potential diversion of opioids.

307. In addition, Walmart, upon information and belief, also distributed and dispensed substantial quantities of prescription opioids in the surrounding area, and these drugs were diverted from the surrounding area into the City. Walmart failed to take meaningful action to stop this diversion despite its knowledge of it, and it contributed substantially to the opioid epidemic in Florida.

308. In the City, Walmart violated the standard of care for a distributor by failing to: (a) control the supply chain; (b) prevent diversion; (c) report suspicious orders; and (d) halt shipments of opioids in quantities it knew or should have known could not be justified and signaled potential diversion.

309. For years, per capita opioid prescriptions in Sarasota County far exceeded the national average and increased in ways that should have alerted Walmart to potential diversion. As a vertically integrated, national retail pharmacy chain, Walmart had the ability to detect diversion in ways third-party wholesale distributors could not by examining the dispensing data from their own retail pharmacy locations.

310. Given the volume and pattern of opioids distributed in Florida and in the City, Walmart was, or should have been aware that opioids were being oversupplied into the state and City and should have detected, reported, and rejected suspicious orders. Yet, the information available shows it did not.

311. Upon information and belief, Walmart, by virtue of the dispensing data available to it, had actual knowledge of indicia of diversion, such as (1) individuals traveling long distances to fill prescriptions; (2) prescriptions for drug "cocktails" known for their abuse potential, such as oxycodone and Xanax; (3) individuals arriving together with identical or nearly identical prescriptions; (4) high percentage of cash purchases; and (5) doctors prescribing outside the scope of their usual practice or geographic area. However, Walmart ignored these obvious red flags.

312. Walmart, therefore, was aware of the suspicious orders that flowed from its distribution facilities. Walmart refused to identify, investigate, and report suspicious orders despite its actual knowledge of drug diversion. Rather, Walmart failed to report suspicious orders, prevent diversion, or otherwise control the supply of opioids flowing into Florida and the City.

313. Upon information and belief, Walmart failed to analyze: (a) the number of opioid prescriptions filled by its pharmacies relative to the population of the pharmacy's community; (b) the increase in opioid sales relative to past years; and (c) the number of opioid prescriptions filled relative to other drugs.

314. Walmart was, or should have been, fully aware that the opioids being distributed and dispensed by it were likely to be diverted; yet, it did not take meaningful action to ensure that it was complying with its duties and obligations with regard to controlled substances, including its responsibility to report suspicious orders and not to ship such orders unless and until due diligence allayed the suspicion.

315. Given Walmart's retail pharmacy operations, in addition to its role as a wholesale distributor, Walmart knew or reasonably should have known about the disproportionate flow of opioids into Florida and the City and the operation of "pill mills" that generated opioid prescriptions that, by their quantity or nature, were red flags for, if not direct evidence of, diversion.

iii. Walmart Failed to Maintain Effective Controls Against Diversion from its Pharmacies in the City

316. Walmart, throughout the relevant time period, owned and operated pharmacies throughout the United States, including pharmacies in the City. Through its wholly owned or controlled subsidiary companies, Walmart operates over 4,500 retail pharmacies across the U.S., a mail-order pharmacy, a specialty pharmacy, and six pharmacy distribution centers that distribute to other Walmart entities.

317. Walmart set policies for its pharmacies at the corporate level. Walmart also presented, through nationwide advertising, a public image of the safety and excellence of all the pharmacists the company hired. In a recruitment video for pharmacists on Walmart's YouTube channel, the company shows Walmart pharmacists speaking about working at the company: "the safety and the excellence we carry to our patients is phenomenal," adding that "the culture that our company has [is] respect for the individual, service, and excellence, and, of course, we always have integrity."[30] The commercial also states that Walmart's pharmacists "strive for excellence" and are "passionate about providing quality healthcare."[31]

[30] Walmart, *Your Career as a Walmart Pharmacist* (Sept. 25, 2014), available at https://www.youtube.com/watch?v=9VD12JXOzfs (last visited May 13, 2020).

[31] *Id.*

318. Walmart pharmacies in and around the City received distributions of prescriptions from Walmart's distribution centers and from other wholesale distributors, which enabled these pharmacies to have the same orders filled by both Walmart and a third-party distributor.

319. As a vertically integrated distributor and dispenser of prescription opioids, Walmart had unique insight into all distribution and dispensing level data, and knew or should have known that it was dispensing an excessive volume of pills into Florida and the City.

320. Discovery will reveal that Walmart knew or should have known that its pharmacies in the City and the surrounding area were: (a) filling multiple prescriptions to the same patient using the same doctor; (b) filling multiple prescriptions by the same patient using different doctors; (c) filling prescriptions of unusual size and frequency for the same patient; (d) filling prescriptions of unusual size and frequency from out-of-state patients; (e) filling an unusual or disproportionate number of prescriptions paid for in cash; (f) filling prescriptions paired with other drugs frequently abused with opioids, like benzodiazepines or prescription "cocktails"; (g) filling prescriptions in volumes, doses, or combinations that suggested that the prescriptions were likely being diverted or were not issued for a legitimate medical purpose; and (h) filling prescriptions for patients and doctors in combinations that were indicative of diversion and abuse. Also, upon information and belief, the volumes of opioids distributed to and dispensed by these pharmacies were disproportionate to non-controlled drugs and other products sold by these pharmacies, and disproportionate to the sales of opioids in similarly sized pharmacy markets. Walmart had the ability, and the obligation, to look for these red flags on a patient, prescriber, and store level, and to refuse to fill and to report prescriptions that suggested potential diversion.

321. Walmart had complete access to all prescription opioid distribution data related to Walmart pharmacies in and around the City.

322. Walmart had complete access to all prescription opioid dispensing data related to Walmart pharmacies in and around the City.

323. Walmart had complete access to information revealing the doctors who prescribed the opioids dispensed in Walmart pharmacies in and around the City.

324. Walmart had complete access to information revealing the customers who filled or sought to fill prescriptions for opioids in Walmart pharmacies in and around the City.

325. Walmart had complete access to information revealing the opioids prescriptions dispensed by Walmart pharmacies in and around the City.

326. Walmart had complete access to information revealing the geographic location of out-of-state doctors whose prescriptions for opioids were being filled by Walmart pharmacies in and around the City.

327. Walmart had complete access to information revealing the size and frequency of prescriptions written by specific doctors across Walmart pharmacies in and around the City.

328. Yet, on information and belief, Walmart did not begin to use this information to identify prescribers of concern or signs of diversion until 2017. Walmart, however, always had the ability to do so. Walmart also failed to put in place effective policies and procedures for the identification of red flags when dispensing opioids and failed to provide adequate guidance or training to its pharmacists on identification of red flags.

329. Even when Walmart pharmacists suspected that an individual prescriber was consistently writing prescriptions for other than a legitimate medical purpose, they could not, for most of the relevant time period, use a "blanket" refusal to fill to refuse all prescriptions from that prescriber. Instead, Walmart pharmacists were required to evaluate and refuse to fill prescriptions on a case-by-case basis. A 2011 document from Walmart Regulatory Affairs regarding the

"Proper Prescriber-Patient Relationship" stated, "Blanket refusals of prescriptions are not allowed. A pharmacist must make an individual assessment of each prescription and determine that it was not issued based on a valid prescriber-patient relationship or a valid medical reason before refusing to fill." The prescription-by-prescription refusal to fill procedure was time-consuming and placed the burden on Walmart and Sam's Club pharmacists, who were already under pressure to fill prescriptions quickly. Moreover, many red flags for diversion are based on prescribing patterns that are readily apparent from aggregate data—for example, the percentage of controlled substance prescriptions compared to non-controlled substances written by a prescriber—but not apparent based on an individual prescription.

330. Finally, in 2017, Walmart implemented a policy by which individual pharmacists could request such blanket refusals, which would permit the pharmacist to refuse to fill future prescriptions from that prescriber without evaluating each prescription individually. In addition, Walmart also always had the ability to "centrally block" problematic prescribers across all Walmart and Sam's Club pharmacies, but did not establish a procedure to do so until 2017. In the "Practice Compliance" document describing this policy, Walmart recognized that its Home Office may, "in certain situations," have information about prescribing practices that is not available to individual pharmacists:

> While pharmacists are in the best position to determine whether individual prescriptions are appropriate, *additional information may be obtained that is not available to our pharmacists*. Therefore, in certain situations, a prescriber may be identified whose prescribing practices raise concerns about prescribing controlled substances for legitimate medical purposes. After a thorough review, these additional insights may lead Walmart to place a block in Connexus on controlled substance prescriptions from these prescribers.

331. Moreover, Walmart's pressure on pharmacists to fill more prescriptions quickly was at odds with a culture and practice of compliance. Incentive awards were tied to the number

of prescriptions a pharmacy filled and profit that the pharmacy generated. Upon information and belief, controlled substances were included in Walmart's pharmacy incentive program for most of the relevant time period. In addition, pharmacists were under constant pressure to increase the number of prescriptions they filled, and to increase the overall percentage of pharmacy sales. As a result, upon information and belief, because of Walmart's drive for speed, pharmacists often did not have enough time to sufficiently review a prescription and conduct the appropriate due diligence.

332. These systemic issues are reflected in numerous enforcement actions and investigations that demonstrate the Walmart put profits and sales ahead of compliance, its customers and communities, and public safety. In 2009, for example, the DEA issued a Show Cause order seeking to revoke the registration of a Walmart pharmacy in California. The order alleged that the pharmacy:

> (1) improperly dispensed controlled substances to individuals based on purported prescriptions issued by physicians who were not licensed to practice medicine in California; (2) dispensed controlled substances . . . based on Internet prescriptions issued by physicians for other than a legitimate medical purpose and/or outside the usual course of professional practice . . . ; and (3) dispensed controlled substances to individuals that [the pharmacy] knew or should have known were diverting the controlled substances.

333. In addition, a 2011 Memorandum of Agreement ("2011 MOA") arising out of the investigation states that the DEA also learned that the same pharmacy was allegedly dispensing controlled substances based on prescriptions that lacked valid DEA numbers and allegedly refilling controlled-substances prescriptions too early.

334. Upon information and belief, the failures described in the 2011 MOA were not limited to California but reflected systemic failures at the corporate level. Indeed, the 2011 MOA,

which required Walmart to maintain a "compliance program" states that it is applicable to "all current and future Walmart Pharmacy locations."

335. Following the 2011 MOA, Walmart was supposed to revamp its dispensing compliance program, but still, its policies and procedures remained deficient.

336. Instead, systemic failures continued, and Walmart's national corporate office not only failed to insist that Walmart implement adequate controls against diversion, they ignored concerns raised by Walmart pharmacists.

337. One internal document from 2015, for example, notes concerns from a Walmart pharmacist that "his leadership would not support his refusing to fill any 'legitimate' (written by a Dr) prescriptions and he stated that his current volume/staffing structure doesn't allow time for individual evaluation of prescriptions[.]" When this pharmacist refused to fill a customer's controlled substance prescription because the customer was attempting to fill it too soon, the Market Health & Wellness Director for that store complained to management that the pharmacist "sent a customer to a competitor" and "expressed significant concern about how 'sending customers away' would impact the sales figures for the store," and insisted that "the store needs to fill every available prescription."

338. In December 2020, the U.S. Department of Justice ("DOJ") filed a lawsuit against Walmart over its opioid dispensing and distribution practices. *United States of America v. Walmart Inc. et al.*, No. 1:20-cv-01744, ECF No. 1 (D. Del. December 22, 2020) ("DOJ Compl."). After a multi-year investigation, and based on a review of millions of pages of documents, much of which was recently produced to the MDL, the DOJ alleged that Walmart pharmacists filled prescriptions issued by "known pill-mill prescribers" and filled "numerous prescriptions that, on their face, showed such obvious red flags . . . that Walmart pharmacists would have known that

the prescriptions had a very high probability of being invalid," in addition to Walmart having a "grossly inadequate suspicious-order monitoring program." *Id.* ¶¶ 22-23, 35. Pharmacists or pharmacy managers would contact Walmart's central compliance personnel for guidance on handling suspected pill mill doctors but felt that their "concerns are falling upon deaf ears." *Id.* ¶ 237. Pharmacists repeatedly sought help from Walmart's corporate office, to no avail. Walmart compliance officials failed to take action in response to these alarms. Instead, they repeatedly sent the same boilerplate response, stating that pharmacists must use their professional judgment but that they must continue to evaluate and refuse to fill on an individual, prescription-by-prescription basis, even in situations where other retail pharmacies had stopped filling any prescriptions from particular prescribers. As a result, Walmart and Sam's Club pharmacies often became channels for illegitimate controlled substance prescriptions from known pill mills. Even in circumstances where a prescriber was under investigation by the DEA, Walmart's compliance department informed pharmacists that would not be a reason to refuse to fill that prescriber's controlled substance prescriptions.

339. The practice of filling prescriptions suspected of being illegitimate, including prescriptions for large quantities of opioids and prescriptions for known "drug cocktails" frequently diverted and abused, was not limited to handful of Walmart and Sam's Club pharmacies. Rather, Walmart had a systemic, national problem. Walmart pharmacists from across the country, including Maine, Massachusetts, Kansas, Washington, Texas, and North Carolina, contacted Walmart's national compliance directors about problem prescribers and suspect prescriptions. One Walmart pharmacist in North Carolina wrote to a Market Health and Wellness Director, in an email subsequently sent to the national compliance department, that "there is no way that many 25 year olds need 120 to 240 oxycodone per month." DOJ Compl. ¶ 324.

Regarding one Texas doctor who was later convicted of illegal distribution of opioids, a Walmart pharmacy manager wrote; "Other chains are refusing to fill for him which makes our burden even greater. *Please help us*." *Id.* ¶174 (emphasis added). Another described the same doctor as a "risk that keeps [him] up at night." *Id.* ¶ 236. Similarly, in September 2016, a Walmart pharmacy manager in Pennsylvania advised that a doctor was "under investigation by the DEA for what we believe is a pill mill operation," and that Rite Aid had begun refusing to fill his prescriptions. *Id.* ¶ 296. The pharmacy manager requested that Walmart put in place a similar "blanket denial," but Walmart's compliance department responded that all prescriptions from that doctor must be evaluated individually. *Id.* Before this particular doctor was indicted in 2017 on nineteen counts including unlawful distribution and dispensing of controlled substances and violations of federal drug laws resulting in the death of five patients, Walmart pharmacies dispensed over 8,000 of his controlled substance prescriptions. *Id.* ¶ 297.

340. Upon information and belief, Walmart also failed to adequately use data available to it to identify doctors who were writing suspicious numbers of prescriptions and/or prescriptions of suspicious amounts or doses of opioids, or to adequately use data available to it to prevent the filling of prescriptions that were illegally diverted or otherwise contributed to the opioid crisis.

341. Upon information and belief, Walmart also failed to adequately analyze and address its opioid sales to identify patterns regarding prescriptions that should not have been filled and to create policies accordingly, or if it conducted such reviews, it failed to take any meaningful action as a result.

D. Defendants' Performance Metrics Put Profits Before Safety

342. Not only did the Chain Pharmacies lack (and fail to implement) adequate policies and procedures to guard against diversion, but Walgreens, and upon information and belief, the other Chain Pharmacies compounded this problem by implementing performance metrics and

prescription quotas for retail stores that contributed to supplying of a black market, including in the City.

343. Defendants also had a responsibility to create a work environment that enables its pharmacy staff to detect and prevent diversion, or at the very least does not undermine the ability of staff to carry out these functions or direct emphasis toward increased sales instead of legal compliance. Accordingly, former DEA diversion investigator Demetra Ashley testified that she believed the duty to provide tools to prevent diversion under Section 1301.71 includes providing a work environment that allows pharmacists to fulfill their corresponding responsibility to fill only legitimate prescriptions. She further agreed as to the importance of adequate staffing and testified that both strict time limits that deprived pharmacists of enough time to investigate red flags and requiring quotas on prescriptions filled sounded unreasonable.

344. In connection with the DEA's investigations described above, the DEA found evidence that Walgreens had a corporate policy encouraging increased sales of oxycodone. As the DEA's September 2012 Order to Show Cause and Immediate Suspension of Registration explains:

> In July 2010, Walgreens's corporate headquarters conducted an analysis of oxycodone dispensing for the prior month at its Florida retail pharmacies and produced an 11 page spreadsheet, ranking all Florida stores by the number of oxycodone prescriptions dispensed in June. The spreadsheet was sent to Walgreens's market pharmacy supervisors in Florida on July 29, 2010, with the admonition that they "*look at stores on the bottom end .... We need to make sure we aren't turning legitimate scripts away. Please reinforce*." A corporate market director of pharmacy operations did reinforce this message to Florida market pharmacy supervisors, highlighting that their "*busiest store in Florida*" was filling almost 18 oxycodone prescriptions per day, yet "We also have stores doing about 1 a day. Are we turning away good customers?"

345. In 2011, a Walgreens project to "Increase Rx Sales and prescription Counts" instructed pharmacies to "improve C2 business" – i.e. dispense more Schedule 2 controlled substances. This focus on *increasing* controlled substance dispensing – including opioids –

continued even after the DEA investigation and $80 million fine. For example, in 2014, the RX Integrity department created a "Pharmacist Controlled Substance Dispensing Opportunities" tool to "identify pharmacists that are dispensing a low rate of controlled substances," and help pharmacists "feel more comfortable in filling controlled substances," specifically focusing on pharmacists dispensing low rates of opioids like "hydromorphone, oxycodone, methadone… hydrocodone," and the cocktail drugs comprising the rest of the "holy trinity" of abuse, such as "carisoprodol… [and] alprazolam."

346. Walgreens also had a bonus program that factored prescription volume into bonus calculations, and served as an incentive for pharmacies and pharmacy technicians to ignore the "red flags" of diversion. The corporate push for speed (or volume) deterred pharmacists from taking the time to properly examine the prescriptions before them and exercising their corresponding responsibility to prevent diversion.

347. Walgreens emphasized in its policies for pharmacist and pharmacy managers: "The best evidence of a well-run pharmacy is the increase in prescriptions and pharmacy sales." One former Walgreens pharmacist described management critiques for "not going fast enough" in dispensing prescriptions and believed "[t]hey'd like you to fill one a minute if you could." She recalled there was even a timer to alert her if she was falling behind, and threats of reduced hours or a move to a different store or location.[32] Indeed, Walgreens had a tool, the "PhLOmometer" that tracked the time to fill a prescription. A March 2013 memo confirms that volume targets included controlled substances as late as 2013 and even after the adopting of the GFD policy. Specifically, the memo states, as the response to an "[a]nticipated question" that "GFD concerns doesn't relieve

[32] *Are Business Tactics at Some Pharmacies Risking Your Health?* (Nov. 8, 2017), https://reachmd.com/news/are-business-tactics-at-some-pharmacies-risking-your-health/1610793/

you from trying to attain the numbers that have been set for you." When considering high schedule 2 dispensing at a particular pharmacy in New Jersey in 2012, as the opiate crisis raged, the pharmacy supervisor pushed back against any attempt to reduce supply of oxycodone, focusing on the impact the reduction would make on filled prescriptions and "the bonus tied to" one pharmacy employee.

348. Such corporate goals obstruct the performance of pharmacists' professional obligations. There is an inherent conflict between performance metrics that pressure pharmacists to fill certain volume of prescriptions, limit customers' wait time, or base pharmacists' incentive pay on customer satisfaction, on the one hand, and the ability to conduct appropriate due diligence to guard against diversion of controlled substances and refuse to fill illegitimate prescriptions even if a customer is dissatisfied, on the other. Defendants have a duty to maintain a corporate culture that promotes and ensures compliance with the law.

349. Defendants maintained no such corporate cultures. Walmart even pushed back when, in 2013, the DEA expressed concerns that bonus incentives for dispensing controlled substances could "lead to bad pharmacist decisions because they know they get will something out of filling scripts." Even though Walmart agreed it should not provide "special" incentives particular to filling controlled substance prescriptions, it resisted excluding controlled substances from incentives also applied with respect to other drugs and does not appear to have excluded controlled substance prescriptions from bonus calculation formulas.

350. In February 2012, Richard Ashworth, then the Vice President of Walgreens' Western Division, supervising over 2,000 Walgreens stores, encouraged stores "to drive for the activities that drive incremental scripts. There are metrics we can improve, today, that we will demonstrate the 'doing whatever it takes' to achieve 100% of FY2011 Script volume," noting "we

are not doing whatever it takes," and particularly that in the "Top 2 complaints" was "Pharmacy Fill was denied."

351. As described further below, pharmacists were expected to meet volume and speed goals. With respect to the volume-based bonus policy, a March 2013 memo confirms that volume targets included controlled substances as late as 2013 and even after the adopting of the GFD policy. Specifically, the memo states, as the response to an "[a]nticipated question" that "GFD concerns doesn't relieve you from trying to attain the numbers that have been set for you."

352. Only as part of its 2013 settlement with the DEA did Walgreens agree to exclude controlled substances calculations from bonus calculations from 2014 forward. This resulted in a 21% reduction in the number of stores purchasing the 80mg OxyContin – evidence that a minimal effort to implement common sense controls had a tangible impact on sales of the most potent controlled substances (although that reduction did not last, as described above, and Walgreens's volume by 2014 had increased again).

353. Even though controlled substances were removed from direct bonus calculations for pharmacists, pharmacists still felt pressured by management to fill prescriptions they were uncomfortable filling, as refusals to fill would impact other store metrics – like customer satisfaction – that impacted management compensation. As one Walgreens pharmacist noted: "As long as Walgreens allows their pharmacists to be evaluated by store managers (who are trained by the Company to be concerned with profit, customer service, and resolving customer complaints), store managers will assert their authority over the pharmacists and will naturally confuse good faith dispensing issues with customer service issues. This is a clear conflict of interest."

354. Walgreens also lobbied against imposition of caps or limits on the volume of prescriptions a pharmacist may fill. As the New York *Times* reported, pharmacists at chain

pharmacies, including Walgreens have "said it had become difficult to perform their jobs safely, putting the public at risk of medication errors," as they "struggle to fill prescriptions, give flu shots, tend the drive-through, answer phones, work the register, counsel patients, and call doctors and insurance companies … all the while racing to meet corporate performance metrics that they characterized as unreasonable and unsafe …."[33] Instead of reducing performance targets, chain pharmacies including Walgreens seek to assign more dispensing tasks to less qualified—and less expensive—pharmacy technicians.

355. Walgreens Pharmacy Managers provided feedback stating that pharmacists did not have enough time to do their work effectively and that a lack of resources kept them from being effective and consistent. The feedback also indicated that pharmacy managers were "[s]truggling to keep our heads above water let alone manage." A consultant hired by Walgreens interviewed pharmacy staff and reported "High Stress" and "errors resulting from stress" and stated "we heard multiple reports of improper behavior" that was "largely attributed to the desire" to meet a corporate metric known as "promise time," which ensures that patients get prescriptions filled within a set amount of time.

356. Without describing individual pharmacies, Daniel Hussar, a nationally-known expert and teacher of pharmacology at Philadelphia's University of the Sciences, commented in the media that the pace and pressure of prescription quotas appeared to be having an impact on accuracy. "The frequency of these errors is increasing greatly," Hussar said; "I've heard some

[33] *See* Ellen Gabler, *How Chaos at Pharmacies Is Putting Patients at Risk*, New York Times, (Jan. 31, 2020), https://www.nytimes.com/2020/01/31/health/pharmacists-medication-errors.html.

pharmacists say, 'It's a blur as to what happened during the day and I can only pray I didn't make any serious mistakes.'"[34]

357. This pressure and focus on profits would not only lead to mistakes, it also would necessarily deter pharmacists from carrying out their obligations to report and decline to fill suspicious prescriptions and to exercise due care in ascertaining whether a prescription is legitimate.

358. Indeed, "a survey by the Institute for Safe Medication Practices (ISMP) revealed that 83% of the pharmacists surveyed believed that distractions due to performance metrics or measured wait times contributed to dispensing errors, as well as that 49% felt specific time measurements were a significant contributing factor."[35]

359. In 2013, the National Association of Boards of Pharmacy (NABP), passed a resolution which cited this survey and additionally stated that "performance metrics, which measure the speed and efficiency of prescription work flow by such parameters as prescription wait times, percentage of prescriptions filled within a specified time period, number of prescriptions verified, and number of immunizations given per pharmacist shift, may distract pharmacists and impair professional judgment" and "the practice of applying performance metrics or quotas to pharmacists in the practice of pharmacy may cause distractions that could potentially

[34] *Are Business Tactics at Some Pharmacies Risking Your Health?*, ReachMD citing ksdk.com (Nov. 8, 2017), https://reachmd.com/news/are-business-tactics-at-some-pharmacies-risking-your-health/1610793.

[35] NAPB, Performance Metrics and Quotas in the Practice of Pharmacy (Resolution 109-7-13) (June 5, 2013), https://nabp.pharmacy/performance-metrics-and-quotas-in-the-practice-of-pharmacy-resolution-109-7-13.

decrease pharmacists' ability to perform drug utilization review, interact with patients, and maintain attention to detail, which could ultimately lead to unsafe conditions in the pharmacy."[36]

360. Still, according to a 2016 investigation by the Chicago *Tribune*, as chain pharmacies increasingly promote quick service, "pharmacists frequently race through legally required drug safety reviews—or skip them altogether," missing dangerous drug combinations in the process.[37] A pharmacist too rushed to check for a potentially deadly drug interaction is also likely to be too rushed to check for red flags of diversion, such as prescription "cocktails" or other combinations of highly abused drugs.

361. According to the *Tribune's* coverage, "Wal-Mart, operator of 4,500 U.S. pharmacies, failed 43 percent of its tests."[38] Walgreens, meanwhile, failed a test of whether pharmacists would dispense dangerous drug combinations without warning patients 30 percent of the time.[39] Further, a Walmart pharmacist commented that she typically filled 200 prescriptions in her daily nine-hour shift, and an even higher volume when working at a different store, equating to two prescriptions per minute.[40]

362. In reporting on the results of its investigation, the *Tribune* quoted Bob Stout, president of the New Hampshire Board of Pharmacy, stating that "'They're cutting corners where they think they can cut."[41] As the report itself explained: "some pharmacies emphasize fast service

---

[36] *Id.*

[37] Sam Roe, Ray Long, and Karisa King, Contract Reporters, *Pharmacies Miss Half of Dangerous Drug Combinations*, Dec. 15, 2016, http://www.chicagotribune.com/news/watchdog/druginteractions/ct-drug-interactions-pharmacy-met-20161214-story.html.

[38] *Id.*

[39] *Id.*

[40] *Id.*

[41] *Id.*

over patient safety. Several chain pharmacists, in interviews, described assembly-line conditions in which staff hurried to fill hundreds of prescriptions a day.[42]

363. "The National Coordinating Council for Medication Error Reporting and Prevention (NCCMERP), also passed a statement advocating for the "elimination of prescription time guarantees and a strengthened focus on the clinical and safety activities of pharmacist within the community pharmacy setting."[43]

364. More recently, a January 2020 New York *Times* article, referenced above, revealed that the problematic performance metrics remain, and have remained, in place. One South Carolina pharmacist advised:

> We are being asked to do things that we know at a gut level are dangerous. If we won't or can't do them, our employers will find someone else who will, and they will likely try to pay them less for the same work.

365. In March 2020, journalists also revealed that Walmart not only ignored reports of suspicious activity from pharmacists concerned that they were filling prescriptions for pill mills, but the company considered these pharmacists' focus misdirected. One internal email, reviewed by ProPublica, showed that in response to a question from a regional manager in 2015 about documenting pharmacists' concerns about doctors believed to be operating pill mills, Walmart Health and Wellness Practice Compliance director Brad Nelson wrote that: "We have not invested a great amount of effort in doing analysis on the data since the agreement [requiring such reporting]

---

[42] *Id.*

[43] National Coordinating Council for Medication Error Reporting and Prevention. Statement Advocating for the Elimination of Prescription Time Guarantees in Community Pharmacy, http://www.nccmerp.org/statement-advocating-elimination-prescription-time-guarantees-community-pharmacy.

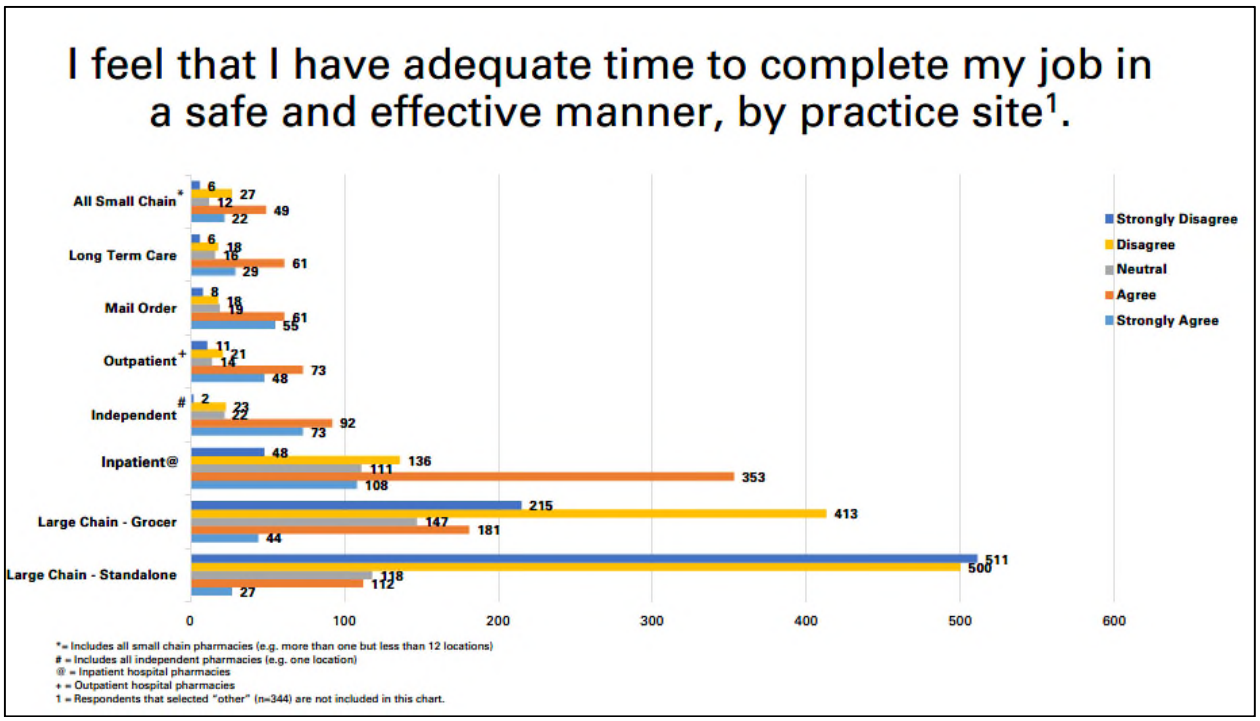
is virtually over. *Driving sales and patient awareness is a far better use of our Market Directors and Market manager's time*."[44]

366. As described above, until 2017, Walmart refused to allow pharmacies to block all prescriptions from doctors whose prescriptions raised red flags that they were running pill mills. Not only did pharmacists have to refuse each prescription on a case-by-case basis, to do so, a pharmacist had to fill out a form that could take as long as twenty minutes, a significant burden when pharmacists were faced with multiple prescriptions from problematic prescribers and the pressure to fill prescriptions quickly.

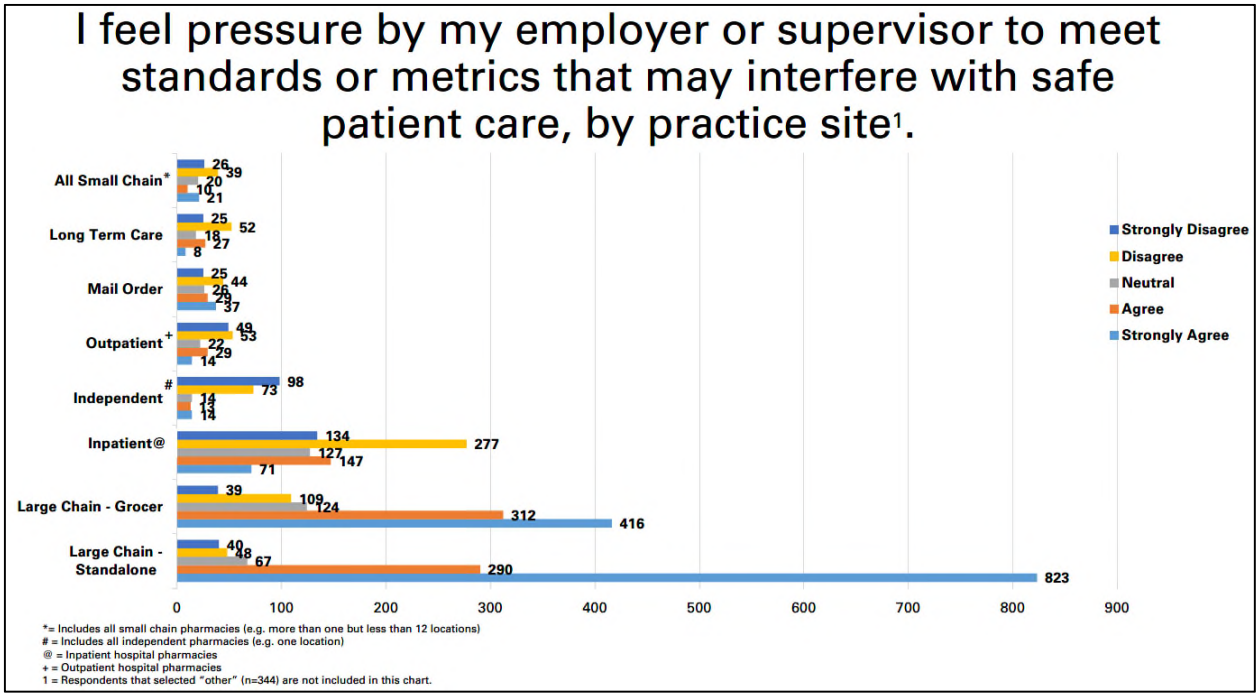
367. An April 2021 workload survey from the Ohio Board of Pharmacy,[45] referenced above, revealed a contrast between the responses of pharmacists at chain pharmacies and pharmacists at other locations concerning the time available to do their job safely:

[44] Jesse Eisinger and James Bandler, *Walmart Was Almost Charged Criminally Over Opioids. Trump Appointees Killed the Indictment.*, ProPublica, (March 25, 2020). https://www.propublica.org/article/walmart-was-almost-charged-criminally-over-opioids-trump-appointees-killed-the-indictment.

[45] https://www.pharmacy.ohio.gov/Documents/Pubs/Reports/PharmacistWorkloadSurvey/2020%20Pharmacist%20Workload%20Survey.pdf



368. The same was true concerning whether standards or metrics were perceived as interfering with patient care:



369. The overwhelming majority of pharmacist comments reported in the survey reflected a belief that chain pharmacies place profit over safety. A common refrain heard from pharmacists was being asked to do more with less—carrying more responsibilities, and facing increased prescription volumes, while, staffing levels have decreased. In a job market filled with new graduates, pharmacists were reminded that they were replaceable. Pharmacists disclosed troubling information not only about their own employers, but also competing chains. A Walmart pharmacist expressed frustration that Walmart was "under the microscope for filling opioids and benzodiazepines" and being told by DEA to "do more," because it was "buying too many controls."

370. Walgreens pharmacists reported the following: "I received my first lunch break last week in the 7 years I have been a pharmacist. I literally have almost passed out multiple times from lack of breaks."[46] "Anytime I would ask for more help or complain, I was told if you don't want this job there are plenty of unemployed pharmacists who will do your same job for less money."[47] "The supervisors are always bending the rules to achieve certain metrics for the company. For instance, Pharmacists make patient calls throughout the day and are expected to reach a certain percentage of people. To help reach this number we are asked to leave messages on patient voicemails telling them if they don't call us back we are to call them again later that day. Many compliance issues are ignored."[48]

[46] *Id.* at 61.

[47] *Id.* at 83.

[48] *Id.* at 89.

E. Defendants Worked Together to Increase Their Profits and Lobbied Against Restrictions on Opioid Use and DEA Enforcement.

371. Beginning as early as the 1990s, outside distributors, largely through the HDA, began to get together with the Chain Pharmacies through NACDS to discuss "concerns regarding statutory requirements to report to DEA what are commonly referred to as suspicious orders."

372. The DEA's suspensions of the registrations of three major distributors in 2007 lit a fuse within the industry. The very real threat of DEA enforcement prompted a flurry of communications between NACDS members and members of the HDA, described above, as well as the now-notorious Pain Care Forum ("PCF"), a forum run by opioid manufacturers. A goal of HDA, which it shared with NACDS, was to "develop a comprehensive DEA strategy" to avoid enforcement actions against distributors.

373. The NACDS and the other trade groups saw their role in influencing diversion policy as being one that was absolutely critical, considering all that was at stake. At times, these groups adopted militaristic strategies and used terminology ironically similar to the "War on Drugs," developing "task forces" and viewing the DEA's crackdown on distributors and chain pharmacies as an assault on the companies themselves. Only this time, the war was being waged against the very regulatory authorities and government entities fighting to deal with the ever-growing problem of abuse and diversion in this country.

To follow up from last week's Pain Care Forum meeting, NACDS is interested in organizing a Task Force to respond to efforts to reschedule combination hydrocodone products into Schedule II. At a minimum, NACDS would like to organize to prepare for the October FDA hearing on this topic, but also would like to be prepared for any additional legislation that may be considered.

NACDS has scheduled a conference call to organize the Task Force on July 26 at 10:30 a.m. The conference call number is: 888-450-5996, pass code: 608936#. Please email Kevin Nicholson at knicholson@nacds.org if you are interested in joining the Task Force but have a conflict for that time.

Kevin N. Nicholson, R.Ph., J.D.
Government Affairs and Public Policy
National Association of Chain Drug Stores
Tel: 703-837-4183

Manufacturers' participation in Defendants' trade groups as a means to effectuate favorable policies is clear when evaluated in the context of how Defendants and other stakeholders viewed the DEA's attempts to curb the opioid epidemic.

I wanted to say hello and I'm sorry that DEA is being so aggressive with this Suspicious Orders stuff.

I heard about your Lakeland, Florida distribution center effective next Monday. They're not going after your Jackson, MS distribution center, are they?

I wish there was something I could do to help in this situation - we are all in the same boat.

Best regards,

Jack

Jack Crowley
Executive Director
CSA Compliance
Purdue Pharma L.P.
One Stamford Forum
Stamford, CT 06901
203-588-8613 (w)
203-273-2656 (c)

374. Walgreens, like the other Defendants, recognized the importance of being able to control and influence trade groups such as the NACDS in the context of influencing policy related to opioid drug abuse and diversion. The efforts taken by the NACDS and other trade groups on behalf of Defendants were so important to their bottom line that Defendants spared no expense in

supporting such groups. Walgreens took a particularly aggressive view of this mutually beneficial relationship, at times, being its top donor across the country.

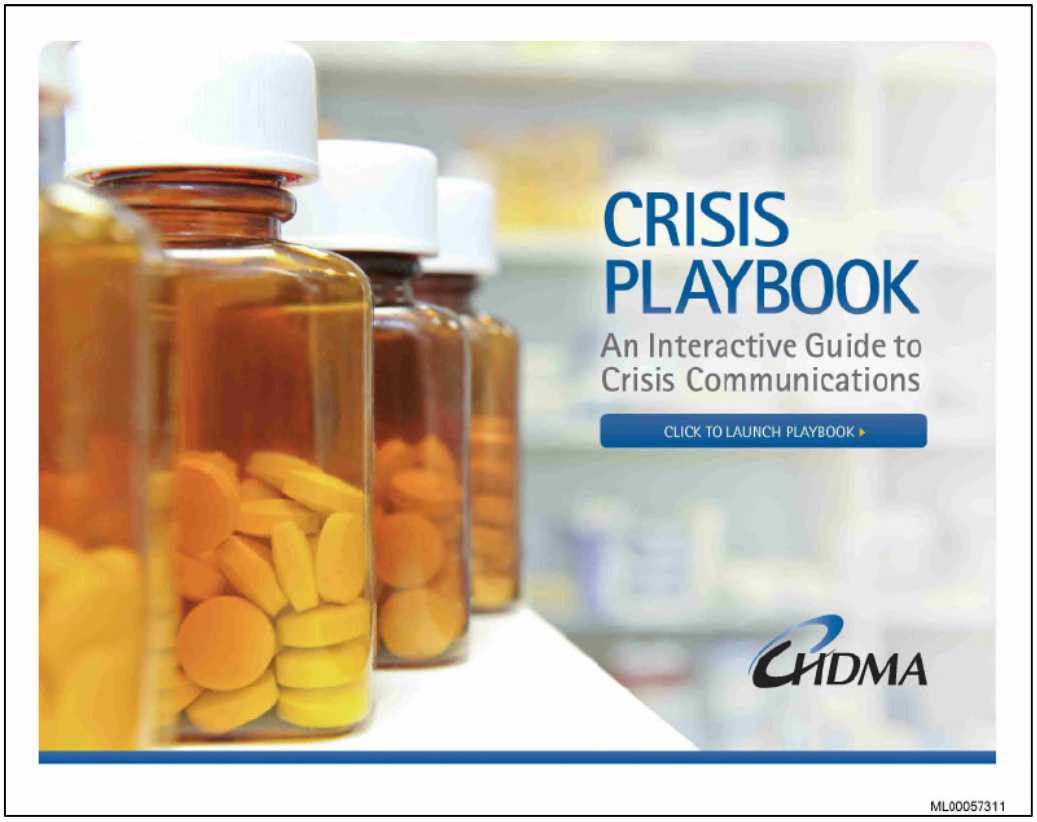
375. NACDS worked with the HDA, the Alliance to Prevent the Abuse of Medicines ("APAM"), and the PCF to support the Marino Blackburn Bill, also known as S.483 or the "Marino Bill." NACDS and Defendants intended the Marino Bill to "tie the hands" of the DEA to actively and aggressively address diversion and compliance with the CSA." NACDS worked together with others in the opioid supply chain to influence the language in the bill to make it most favorable for them and more restrictive on the DEA. Notably, masking the influence of industry, when the APAM was asked to sign on to a 2014 letter of support it was "signed by the Alliance, ***not the individual members***." The final letter that was sent to Senators Hatch and Whitehouse was signed by the members of the Pain Care Forum as well as the Alliance, the NACDS, American Academy of Pain Management, and U.S. Pain Foundation.

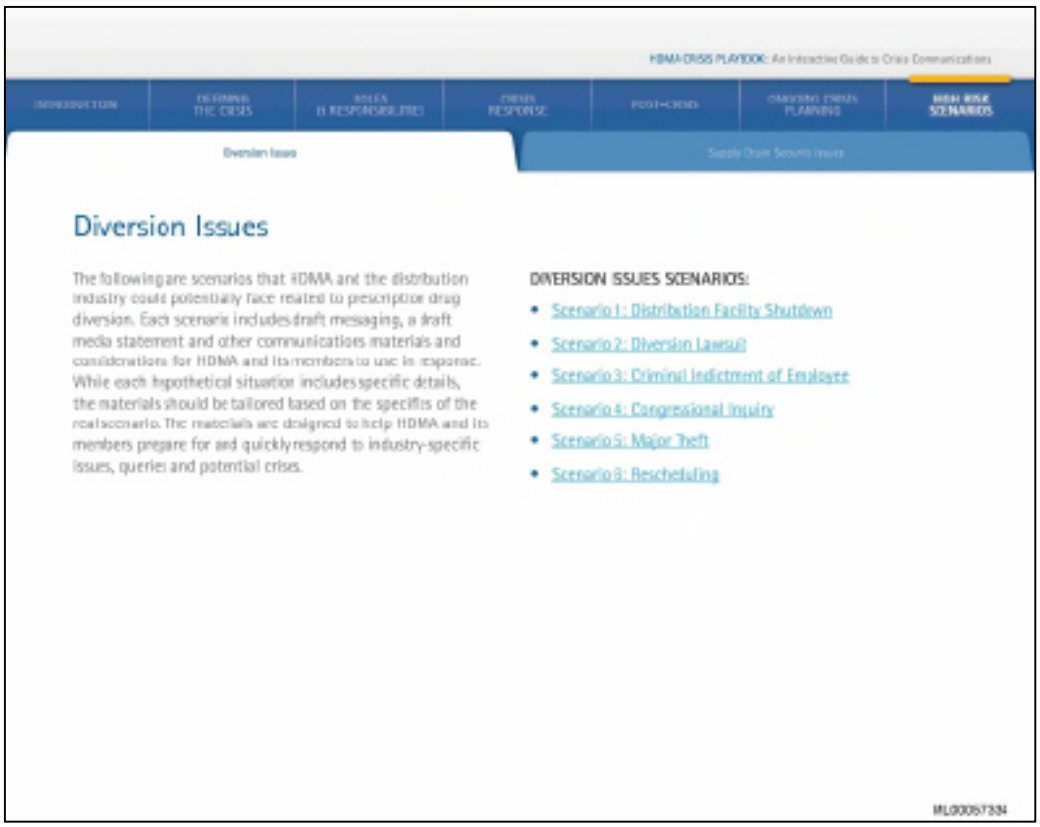
376. The Marino Bill effectively removed the DEA's ability to issue immediate suspension orders regarding manufacturer or distributor registrations. It also permitted a non-compliant registrant an opportunity to cure its noncompliance before the DEA could take enforcement action and changed the standard upon which revocation occurred. In the midst of a growing opioid crisis, the Marino Bill removed the most effective deterrent and constrained DEA enforcement actions.

377. In August of 2011, NACDS worked with others on a joint letter opposing DEA fee increases for registrants that were intended to fund the "hir[ing of] more agents and do[ing] more inspections."

378. HDA's Crisis Playbook, developed in 2013, was a direct response to the "threats" perceived by HDA's members and affiliates, including Defendants, to their bottom line: profits

derived from the distribution and sale of prescription opioids. Defendants did and continue to rely on and employ the strategies discussed in the Crisis Playbook. Curiously, there are no slides on how best HDA and its members, including Defendants, might work to curb the crisis that is the opioid epidemic.





379. In 2016, the NACDS Policy Council discussed ongoing efforts to shape opioid legislation, including their success in removing a requirement that pharmacists have to check their state drug monitoring program before filling controlled prescriptions. NACDS also fought regulatory efforts to require Defendants to use available dispensing related data and red flags to prevent diversion, opposing what it described as "recent DEA actions in which DEA is expecting pharmacists to be enforcement agents with respect to prescriptions for pain medications.

380. NACDS and HDA sought to slow down and impede DEA enforcement activities by requiring the DEA to "work with the [Food and Drug Administration] FDA on all drug diversion issues," ostensibly on the grounds that the DEA's diversion enforcement activities – including "clos[ing] drug distribution centers and pharmacies" and "actions against pharmacies" were harmful in "leading to patients not being able to receive their medications." This purported concern, however, was industry code for impediments to sales.

381. NACDS and HDA agreed that the pharmacies should "be more aggressive" and "lead the charge" with respect to certain DEA issues. NACDS members coordinated regarding pharmacy diversion and "DEA red flags" through a "DEA Compliance Workgroup." Defendants further used a NACDS "Pharmacy Compliance Roundtable" to discuss avoiding criminal and civil liability for issues related to controlled substances, SOM, and diversion. And, in May 2012, the NACDS formed a Policy Council "Task Group" to "discuss issues and develop strategies" concerning "ongoing problems that NACDS members are having with DEA enforcement actions," through which it sought to influence the government and media set meetings with legislators seeking to "address the problems with DEA actions," and "collaborate with, and support others' efforts" including HDA.

382. NACDS members coordinated regarding pharmacy diversion and "DEA red flags" through a "DEA Compliance Workgroup." Defendants further used a NACDS "Pharmacy Compliance Roundtable" to discuss avoiding criminal and civil liability for issues related to controlled substances, SOM, and diversion. And, in May 2012, the NACDS formed a Policy Council "Task Group" to "discuss issues and develop strategies" concerning "ongoing problems that NACDS members are having with DEA enforcement actions," through which it sought to influence the government and media, set meetings with legislators seeking to "address the problems with DEA actions," and "collaborate with, and support others' efforts" including HDA.

F. Defendants Also Entered into Joint Ventures that Further Undermined their Outside Vendors' Incentive to Conduct Due Diligence, While Increasing their Own Access to Information.

383. The collaboration between Defendants and other industry partners extended beyond their mutual interest in limiting regulations and enforcement that constrained their ability to sell opioids. Indeed, the companies had direct financial relationships that, quite literally, invested them in each other's success.

384. As described above, Walgreens entered into an exclusive arrangement with AmerisourceBergen as its supplier, with Walgreens obtaining both equity in AmerisourceBergen and a seat on its Board. As part of a three-year extension of that arrangement, in 2016, the two agreed to include a requirement that AmerisourceBergen "make certain working capital investments in the relationship and will proceed with additional capital investments in its distribution network."

385. The merger between Walgreens and AmerisourceBergen had begun in 2012, when the two formed Walgreens Boots Alliance Development, a joint venture based in Switzerland. AmerisourceBergen was described as being able to gain from Walgreens's "purchasing synergies," through the companies' relationship.

386. In 2016, McKesson and Walmart formed ClarusOne Sourcing Services LLP to source generic pharmaceuticals for their respective U.S. operations. As part of this "partnership," McKesson and Walmart "established an organization in London to provide strategic sourcing services for both companies," according to a job posting on McKesson's website.

387. Given that Walgreens and Walmart, on the one hand, the largest wholesalers, on the other, considered themselves partners invested in one another's success, they had even less incentive to turn away from the blind deference the Chain Pharmacies received when buying and selling controlled substances.

G. Defendants Worked with Opioid Manufacturers to Promote Opioids and Improperly Normalize Their Widespread Use.

388. The Chain Pharmacies not only failed to check the oversupply of opioids by violating laws and ignoring available safety measures, they were also a critical participant in the manufacturers' and distributors' campaign to create a sea change in the way opioid were utilized in the United States. This campaign included spreading false messaging about the addictive nature

of prescription opioids, creating the false perception that opioids should be widely utilized, actively promoting widespread opioid utilization, improperly increasing opioid sales beyond legitimate uses, and dismantling and undermining the last line of defense that was supposed to exist at the pharmacy level.

389. As Purdue astutely recognized, the Chain Pharmacies were critical to the campaign to promote prescription opioid us, noting in internal documents:

> The pharmacist plays a vital role in pain management, as they are the last piece of the puzzle in getting patients prescriptions filled. If the pharmacist is not educated in the use of OxyContin or has any misconceptions about the use of opioids, it can result in a prescription not getting filled and a patient suffering from needless pain.
>
> The pharmacist is the ultimate gate keeper. At times, they can make or break the effective use of Oxycontin. We are running into several cases of legal and regulatory issues, which has resulted in counter detailing of Oxycontin. Much of this is borne out of ignorance.
>
> The absolute last thing we want is for the OxyContin prescription to be bounced out at the pharmacy level because of unfounded fears from the "uneducated" pharmacist.

390. Instead of playing the critical gatekeeper role that the Chain Pharmacies were supposed to play, they instead helped open the floodgates of dangerous opioid narcotics flooding into communities like the City. The Chain Pharmacies participated in the multi-faceted campaign to spread misinformation about opioids and improperly increase the utilization and supply of opioids including by:

a. Spreading false messages to pharmacists and patients through provider and patient "education" campaigns designed to improperly normalize widespread use of opioids;

b. Direct marketing of opioids to patients, pharmacists and healthcare providers;

c. In-store advertisements and advertising campaigns designed to drive sales of prescription opioids;

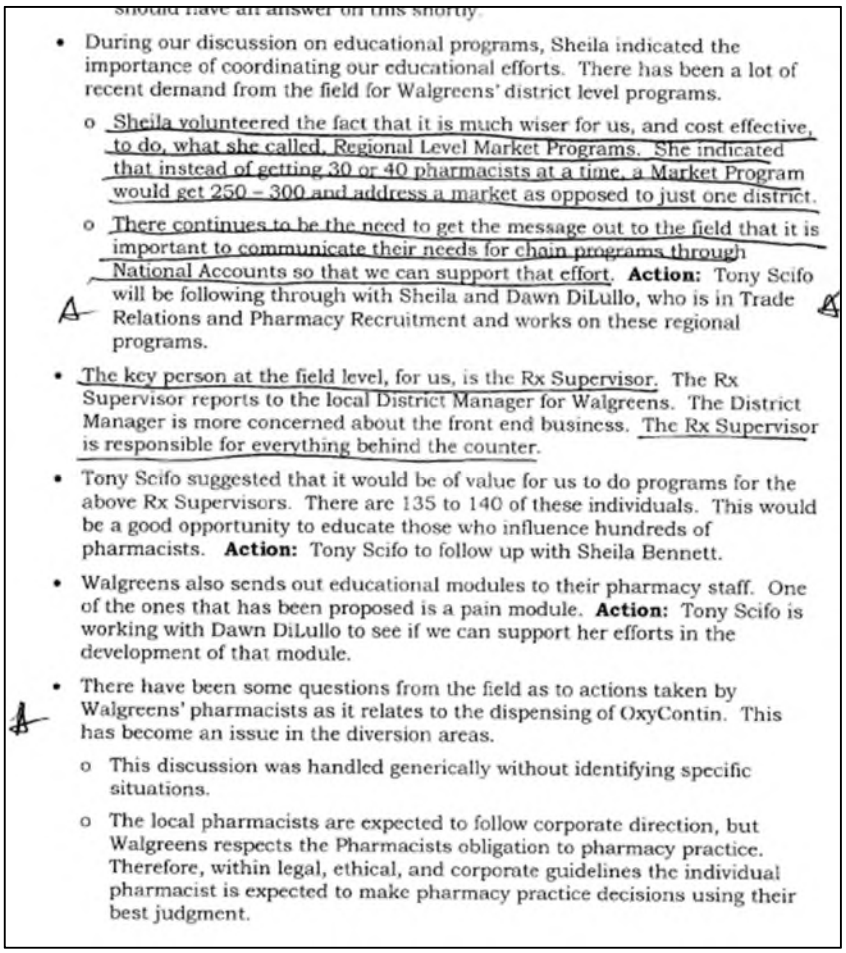
d. Use of financial incentives such as coupon programs, rebate programs, and loyalty programs designed to drive opioid sales; and

e. Driving the sale of opioid products through patient adherence programs designed to generate long-term opioid use.

391. Starting in the 1990s, opioid manufacturers created a carefully orchestrated campaign to change the utilization of prescription opioids in the United States. The Chain Pharmacies played a critical role in that campaign. Indeed, for that campaign to work, the thousands of pharmacists employed by the Chain Pharmacies and the patients they serviced had to be conditioned to accept the sea change in the use of opioids and be "re-educated" about their dangers. In order for prescription opioids to achieve the blockbuster sales that occurred, their widespread had to be normalized not only with doctors but also with patients and pharmacists.

392. Defendants worked as partners and conduits to spread the misinformation campaign orchestrated by opioid manufacturers to pharmacists and patients across the country, including the false messaging surrounding the use of opioids for the treatment of chronic pain and the true addictive nature of opioids, all in an effort to increase profits for all stakeholders.

393. Working with Purdue as early as 2001, Walgreens played a pivotal role in expanding the market and ensuring the demand and supply for prescription opioids would grow to tragic proportions. Purdue was particularly interested in using what Walgreens described to Purdue as its Regional Level Market Programs to educate pharmacists and patients on the benefits of Purdue's OxyContin.



should have an answer on this shortly.

- During our discussion on educational programs, Sheila indicated the importance of coordinating our educational efforts. There has been a lot of recent demand from the field for Walgreens' district level programs.
  - Sheila volunteered the fact that it is much wiser for us, and cost effective, to do, what she called, Regional Level Market Programs. She indicated that instead of getting 30 or 40 pharmacists at a time, a Market Program would get 250 – 300 and address a market as opposed to just one district.
  - There continues to be the need to get the message out to the field that it is important to communicate their needs for chain programs through National Accounts so that we can support that effort. **Action:** Tony Scifo will be following through with Sheila and Dawn DiLullo, who is in Trade Relations and Pharmacy Recruitment and works on these regional programs.
- The key person at the field level, for us, is the Rx Supervisor. The Rx Supervisor reports to the local District Manager for Walgreens. The District Manager is more concerned about the front end business. The Rx Supervisor is responsible for everything behind the counter.
- Tony Scifo suggested that it would be of value for us to do programs for the above Rx Supervisors. There are 135 to 140 of these individuals. This would be a good opportunity to educate those who influence hundreds of pharmacists. **Action:** Tony Scifo to follow up with Sheila Bennett.
- Walgreens also sends out educational modules to their pharmacy staff. One of the ones that has been proposed is a pain module. **Action:** Tony Scifo is working with Dawn DiLullo to see if we can support her efforts in the development of that module.
- There have been some questions from the field as to actions taken by Walgreens' pharmacists as it relates to the dispensing of OxyContin. This has become an issue in the diversion areas.
  - This discussion was handled generically without identifying specific situations.
  - The local pharmacists are expected to follow corporate direction, but Walgreens respects the Pharmacists obligation to pharmacy practice. Therefore, within legal, ethical, and corporate guidelines the individual pharmacist is expected to make pharmacy practice decisions using their best judgment.

In fact, Purdue leveraged its relationship with Walgreens and their mutually beneficial goal of growing the opioid business to ensure that Purdue had input into Walgreens "***corporate guidelines***" to which Walgreens pharmacists were "expected to follow" when it came to the dispensing of prescription opioids.

394. Walgreens also used its corporate oversight abilities to identify stores it believed were not filling enough oxycodone to make sure they weren't "turning away good customers" and encouraging stores to utilize continuing education created by opioid manufacturers to inform their decisions regarding dispensing.

395. Starting in at least 1999, Purdue sponsored Walgreens's Pharmacy continuing education programs designed to encourage stores to "get on the Pro Pain Management Band

Wagon." Purdue was thrilled with the response and assistance it received from Walgreens when Purdue presented on "Pain Management for the Pharmacist." At the beginning of each Purdue sponsored meeting, a Walgreens pharmacist made a presentation on his store and the program implemented. His store actively advertised to area doctors and patients that they were a "full-service" pain management pharmacy. This service included providing a list to physicians' offices of all CIIs they had in stock (and they had everything), accepting "verbal orders" for Class II analgesics prior to presentation of the original prescription at the store to decrease "waiting time", allowing partial fills on CII prescriptions in terminal patients, and accepting after hours "emergency CII prescriptions" without a hassle. Purdue praised the pharmacist's actions as "fantastic."

396. Walgreens's use of pro-opioid continuing education continued as the opioid crisis grew. For example, Walgreens's Market Director of Pharmacy Operations recommended that Walgreens District Managers and Pharmacy Supervisors attend a continuing education program titled "The Pharmacists' Role in Pain Management: A Legal Perspective," which was available on-line at RxSchool.com. This program was one in a long line of pharmacist "education" programs, or CEs, that opioid manufacturer Purdue developed as part of its strategy to disseminate "a new school of thought" about opioids. Through these programs, Purdue and the Chain Pharmacies disseminated fraudulent information that redefined the red flags of abuse or diversion in an effort to correct pharmacists' "misunderstanding" about pain patients and the practice of pain management. Purdue took what it called an "aggressive role" in the education of Walgreens's and other pharmacists on pain management issues.

397. Walgreens's Market Director of Pharmacy Operations also recommended a second continuing education program titled "Navigating the Management of Chronic Pain: A Pharmacist's

Guide." The second "CE" incorporated into Walgreens's dispensing training program, "Navigating the Management of Chronic Pain: A Pharmacist's Guide" was sponsored by opioid manufacturer Endo Pharmaceuticals and disseminated manufacturer messaging designed to broaden the market for opioids. For example, it stated "according to most reports, approximately 30% of the population lives with chronic pain" and citing, *inter alia*, another CE presentation sponsored by the American Pain Society (another known front-group). It also claimed that "most opioid adverse effects can be managed with careful planning and patient education." It went on to discuss "fears and prejudices" related to addictive behaviors that "unnecessarily limit" opioid use, described as "opiophobia" which the piece claimed was the result of "misunderstandings regarding the concepts of addiction, physical dependence, and tolerance."

398. One of the presenters for this Endo sponsored CE was Kenneth C. Jackson. Mr. Jackson was a frequent speaker and Key Opinion Leader ("KOL") for Purdue. Mr. Jackson also co-authored the CE program titled "Use of Opioids in Chronic Noncancer Pain," which was sponsored by Purdue. Released in April 2000, it was designed to eliminate "misconceptions about addiction, tolerance and dependence" and contained many of the same messages as the pharmacist guide he authored.

399. Walgreens also presented the video, The Pharmacist's Role in Pain Management - A Legal Perspective, at mandatory meetings for pharmacy managers. This continuing education program ("CE") was also sponsored by Purdue, was similar to the earlier presentations, and was further disseminated to Walgreens pharmacists in June 2011. Released in 2009, the program was presented by Jennifer Bolen, JD. Ms. Bolen was a frequent speaker for Purdue and other opioid manufacturers, served as Special Counsel for the American Academy of Pain Medicine (a known

front group for opioid manufactures), acted as a Key Opinion Leader ("KOL") for Purdue, and was described by Purdue as "a pain patient who takes opioids."

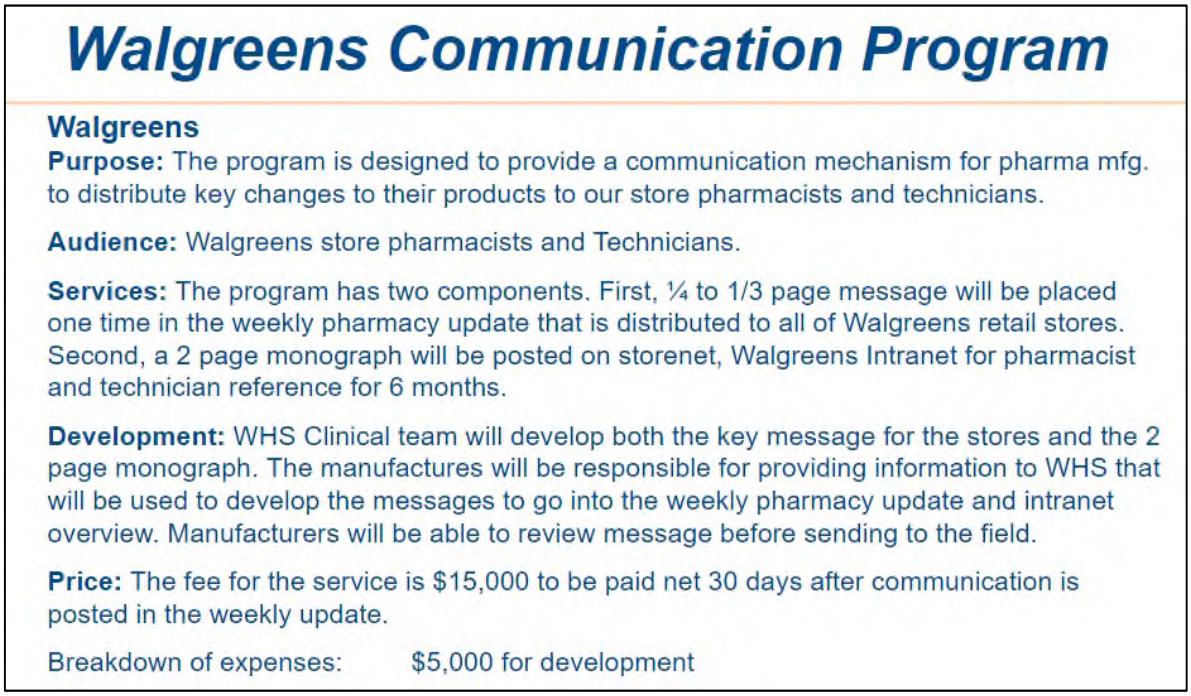
400. Armed with information gleaned from Purdue sponsored CE, the Walgreens pharmacists who had temporarily stopped filling controlled substances prescriptions began to accept them again.[49] It is no surprise that in 2013 Walgreens acknowledged that several of the stores that touted this CE as part of their controlled substance action plan dispensed "certain controlled substances in a manner not fully consistent with its compliance obligations under the CSA."

401. Similarly, Walmart teamed up with Purdue to spread misinformation about prescription opioids. As early as 1995, Purdue and Walmart launched presentations utilizing pro-opioid key opinion leaders to pharmacists across the country. As Purdue described: "The Program [on pain management] will originate from Walmart's Studios in Bentonville, AR and sent by satellite to more than 2,000 stores across the country. It is expected that as many as 4,000 pharmacists and district managers will either attend the session or view the video tape."

402. The Chain Pharmacies coordinated marketing efforts to their pharmacists and staff regarding opioids at trade shows and through email blasts, mailers, and brochures to promote the idea that opioids were safe for widespread utilization, that pain was undertreated, and the appropriate treatment of pain were opioid drugs.

[49] WAGFLDEA00001011 ("After having received the CE presentation that you put on, along with the presentation by the Pain Clinic at our pharmacy manager meeting, Megan went and visited the pain clinics surrounding her store. Of the three, she feels very comfortable with two of the clinics, and accepts all prescriptions from them (minus any natural concerns: early refills, patient condition, etc that occurs with all stores").

403. Opioid manufacturers paid the Chain Pharmacies to conduct internal marketing to pharmacists and pharmacy staff. For example, internal documents from Janssen illustrate the reach the Chain Pharmacies could offer for opioid manufacturers' marketing messages:



Walgreens Communication Program

Walgreens

Purpose: The program is designed to provide a communication mechanism for pharma mfg. to distribute key changes to their products to our store pharmacists and technicians.

Audience: Walgreens store pharmacists and Technicians.

Services: The program has two components. First, ¼ to 1/3 page message will be placed one time in the weekly pharmacy update that is distributed to all of Walgreens retail stores. Second, a 2 page monograph will be posted on storenet, Walgreens Intranet for pharmacist and technician reference for 6 months.

Development: WHS Clinical team will develop both the key message for the stores and the 2 page monograph. The manufactures will be responsible for providing information to WHS that will be used to develop the messages to go into the weekly pharmacy update and intranet overview. Manufacturers will be able to review message before sending to the field.

Price: The fee for the service is $15,000 to be paid net 30 days after communication is posted in the weekly update.

Breakdown of expenses: $5,000 for development

404. These are but some examples. Since acting as a key participant in the expansion of the market and normalization of prescription opioids in the 1990s and 2000s, for decades, the Chain Pharmacies, particularly Walgreens and Walmart, continued to offer "education" programs designed to grow and maintain the market for prescription opioids by changing perceptions of pharmacists and staff so that the "last line of defense" to increased opioid supply would be relaxed and sales would occur without restriction.

405. This pervasive misinformation campaign was critical to the dramatic shift in the way opioids were utilized in the United States and was a key factor in creating the dramatic oversupply of opioids into the United States and Plaintiff's community. The Chain Pharmacies played a key role in that campaign.

H. Defendants Delayed a Response to the Opioid Crisis by Pretending to Cooperate with Law Enforcement

406. When a distributor does not report or stop suspicious orders, or a pharmacy fails to maintain effective policies and procedures to guard against diversion, prescriptions for controlled substances may be written and dispensed to individuals who abuse them or who sell them to others to abuse. This, in turn, fuels and expands the illegal market and results in opioid-related overdoses. Without reporting by those involved in the supply chain, law enforcement may be delayed in taking action—or may not know to take action at all.

407. Despite their conduct in flooding Florida and other states with dangerous and unreasonable amounts of opioids, Defendants publicly portrayed themselves as committed to working with law enforcement, opioid manufacturers, and others to prevent diversion.

408. In its 2011 MOA, Walgreens agreed to undertake several different anti-diversion measures. Yet, as a DEA official explained in a subsequent Order to Show Cause and Immediate Suspension of its registration that was issued a mere month later and pertained to Walgreens's Jupiter Florida Distribution Center, Walgreens's "anti-diversion" measures appeared to be primarily self-serving:

> [W]hen a company undertakes to survey its stores for regulatory compliance, then selectively edits that survey for the explicit purpose of avoiding evidence of its own non-compliance, as Walgreens apparently did in May 2011, claims of effective remedial measures have less credibility. I gave significant weight to the fact that Walgreens appears to have deliberately structured certain of its antidiversion measures to avoid learning about and/or documenting evidence consistent with diversion. At best, I regard this as deliberate indifference on Walgreens'[s] part as to its obligations as a DEA registrant.
>
> My confidence in Walgreens'[s] remedial measures is lessened further by the fact that this manipulation of the compliance survey occurred just one month after Walgreens entered into a nationwide Memorandum of Agreement (MOA) with DEA to resolve an Order to Show Cause issued to a San Diego Walgreens pharmacy based on

> allegations of unlawful dispensing. . . . Walgreens'[s] effort to enact . . . [a compliance] program in Florida appears to have been, in part, intentionally skewed to avoid actually detecting certain evidence of possible diversion.

409. Despite the behavior described above, Walgreens nevertheless publicly portrayed itself as committed to working with law enforcement, opioid manufacturers, and others to prevent diversion of these dangerous drugs.

410. In August of 2018, after journalists at the Washington *Post* disclosed information gleaned from the ARCOS data regarding the staggering number of opioids Walgreens distributed and sold, Walgreens again publicly promoted itself as being and "ha[ving] been an industry leader in combatting this crisis in the communities where our pharmacists live and work." Walgreens further asserted that "Walgreens pharmacists are highly trained professionals committed to dispensing legitimate prescriptions that meet the needs of our patients."[50]

411. Yet, in January 2020, Walgreens released a Board Report on Oversight of Risks Related to Opioids. There, it claimed that: "In recent years, the Company has implemented a number of operational changes that it believes have helped to reduce its risk with respect to its dispensing of prescription opioids. The Company is focused on the continuous improvement of its controlled substances compliance program, implementing enhancements to prevent, identify and mitigate the risk of non-compliance with federal and state legal requirements."[51] It went on to tout its "Good Faith Dispensing policy," as "provid[ing] the foundation for our pharmacists to

[50] Aaron C. Davis & Jenn Abelson, *Distributors, pharmacies and manufacturers respond to previously unreleased DEA data about opioid sales*, Washington Post (Aug. 8, 2019), https://www.washingtonpost.com/investigations/distributors-pharmacies-and-manufacturers-respond-to-previously-unreleased-dea-data-about-opioid-sales/2019/07/16/7406d378-a7f6-11e9-86dd-d7f0e60391e9_story.html.

[51] https://s1.q4cdn.com/343380161/files/doc_downloads/governance_guidelines/Board-Report-on-Oversight-of-Risk-Related-to-Opioids-June-2019-rev.-August-2019.pdf.

understand their roles and responsibilities when dispensing prescriptions for controlled substances."[52] It also claimed that "the Company conducts its own voluntary, independent review of controlled substance purchase orders placed by our pharmacies, providing an additional layer of review above and beyond the legally required monitoring performed by the wholesalers."[53] There, Walgreens's Board acknowledged that the "fundamental elements of an effective compliance program include," among other things, "[w]ritten policies, procedures, and standards of conduct setting forth the Company's expectations and requirements for operating all business activities in an ethical and compliant manner"; "[o]versight of the Compliance Program by the Global Chief Compliance and Ethics Officer, Compliance and Ethics Officers for each operating division, and Compliance and Governance Committees"; and, "[a]uditing and monitoring."[54]

412. With respect to compensation, the Board stated: "[w]e have a strong pay-for-performance philosophy." Accordingly, its "Compensation and Leadership Performance Committee," the Board explained, "aims to incent leaders to support the Company's culture and model desired behaviors, ensuring ethical behavior and mitigating risks, through ongoing monitoring, reviewing and governance of all incentive plans."[55]

413. Yet, at the end of January 2020, the New York *Times* revealed that Walgreens had not reformed its policies putting speed ahead of safety and pharmacists continued to feel pressed to do more with less. According to the article, pharmacists at Walgreens stores "described understaffed and chaotic workplaces where they said it had become difficult to perform their jobs

[52] *Id.*

[53] *Id.*

[54] *Id.*

[55] *Id.*

safely, putting the public at risk of medication errors."[56] The article explained that these pharmacists "struggle to fill prescriptions, give flu shots, tend the drive-through, answer phones, work the register, counsel patients and call doctors and insurance companies," while "racing to meet corporate performance metrics that they characterized as unreasonable and unsafe in an industry squeezed to do more with less."[57]

414. Citing company documents, the article showed that Walgreens continues to tie bonuses to achieving performance metrics. Walgreens, in response stated that errors were rare and that "it made 'clear to all pharmacists that they should never work beyond what they believe is advisable.'"[58]

415. Following its Texas settlement, Walmart claimed that the agreement pertained to a small number of stores in that state and claimed that Walmart was "eager to comply with the law."[59] A Walmart spokesperson further claimed that: "We take record keeping seriously[,]" and "[w]e continuously review our processes at our pharmacies to ensure they are accurate and in full compliance with the law."[60]

416. More recently, Walmart reportedly claimed to be cooperating with a federal investigation and "taking action to fix its opioid dispensing practices."[61] In fact, however, Walmart

---

[56] Ellen Gabler, *How Chaos at Pharmacies Is Putting Patients at Risk*, New York Times, (Jan. 31, 2020), https://www.nytimes.com/2020/01/31/health/pharmacists-medication-errors.html.

[57] *Id.*

[58] *Id.*

[59] Associated Press, *Wal-Mart Settles Drug Records Accusation*, (Jan 7, 2009), http://prev.dailyherald.com/story/?id=262762.

[60] *Id.*

[61] Jesse Eisinger and James Bandler, *Walmart Was Almost Charged Criminally Over Opioids. Trump Appointees Killed the Indictment.*, ProPublica, (March 25, 2020),

subsequently "acknowledged that it halted its cooperation in mid-2018."[62] And as noted above, the DOJ has filed suit against Walmart for its opioid distribution and dispensing practices.

417. Moreover, in furtherance of their effort to affirmatively conceal their conduct and avoid detection, all Defendants through the joint amicus brief filed by the HDA and NACDS in *Masters Pharmaceuticals*, described above, made the following statements:[63]

> "HDMA and NACDS members not only have statutory and regulatory responsibilities to guard against diversion of controlled prescription drugs, but undertake such efforts as responsible members of society."
>
> "Distributors take seriously their duty to report suspicious orders, utilizing both computer algorithms and human review to detect suspicious orders based on the generalized information that is available to them in the ordering process."

418. NACDS, in response to media coverage concerning pharmacy working conditions and safety concerns, said that "'pharmacies consider even one prescription error to be too many' and 'seek continuous improvement.'"[64] NACDS also claimed one should not "assume cause-effect relationships" between errors and the workload of pharmacists such as "distraught pharmacists" who conveyed concerns to state boards and associations "in at least two dozen states."[65]

419. The NACDS also filed an amicus brief supporting Walmart's motion to dismiss in the DOJ action described above.

---

https://www.propublica.org/article/walmart-was-almost-charged-criminally-over-opioids-trump-appointees-killed-the-indictment.

[62] *Id.*

[63] Brief for HDMA and NACDS, 2016 WL 1321983, at *3-4, 25.

[64] Ellen Gabler of the New York Times, Pharmacists at CVS, Rite Aid and Walgreens Are Struggling With Understaffed and Chaotic Workplaces, Chicago Tribune (Feb. 3, 2020), https://www.chicagotribune.com/business/ct-biz-nyt-pharmacy-mistakes-20200201-wp2ftrt2sjhfvjwnmwbtnl3y3i-story.html

[65] *Id.*

420. Through the above statements made on their behalf by their trade association, and other similar statements assuring its continued compliance with their legal obligations, Defendants not only acknowledged that they understood their obligations under the law, but further affirmed that their conduct was in compliance with those obligations. In doing so, Defendants further delayed efforts to address the growing opioid epidemic.

I. Multiple Enforcement Actions Against the Chain Pharmacies Confirm Their Compliance Failures

421. The Chain Pharmacies have long been on notice of their failure to abide by state and federal law and regulations governing the distribution and dispensing of prescription opioids. Indeed, several of the Chain Pharmacies have been repeatedly penalized for their illegal prescription opioid practices. Upon information and belief, based upon the widespread nature of these violations, these enforcement actions are the product of, and confirm, the failures of national policies and practices of the Chain Pharmacies.

1. Walgreens

422. Walgreens is the second-largest pharmacy store chain in the United States behind CVS, with annual revenue of more than $118 billion. According to its website, Walgreens operates more than 8,100 retail locations and filled 990 million prescriptions on a 30-day adjusted basis in fiscal 2017.

423. Walgreens also has been penalized for serious and flagrant violations of the CSA. Indeed, Walgreens agreed to the largest settlement in DEA history at the time—$80 million—to resolve allegations that it committed an unprecedented number of recordkeeping and dispensing violations of the CSA, including negligently allowing controlled substances such as oxycodone and other prescription painkillers to be diverted for abuse and illegal black market sales. These

actions demonstrate Walgreens's knowledge of, and disregard for, its obligations to prevent diversion.

424. On September 30, 2009, the DEA issued an Order to Show Cause against a Walgreens retail facility in San Diego, California based in part on allegations that it was dispensing controlled substances, including opioids, to individuals that it knew or should have known were diverting the controlled substances. Although the Order addressed this specific location, the response, including Walgreens's internal assessment of its compliance, or lack thereof, revealed systemic failures from which its pharmacies in the City would not have been exempt.

425. In April 2011, Walgreens entered into an Administrative Memorandum of Agreement ("2011 MOA") with the DEA arising from the San Diego OTSC and expressly agreed that it would "maintain a compliance program to detect and prevent diversion of controlled substances as required under the CSA and applicable DEA regulations" including regarding the dispensing practices at all of its nationwide pharmacies.

426. On September 14, 2012, however, the DEA also issued an *Order to Show Cause and Immediate Suspension Order* ("ISO"), described above against Walgreens's Distribution Center in Jupiter, Florida, as well as Orders to Show Cause related to certain Walgreens pharmacies. Evidencing the existence of systemic failures, the ISO stated that, "[DEA's] concerns with [Walgreens'] distribution practices are not limited to the six Walgreens pharmacies [discussed in the ISO]."

427. In 2013, Walgreens agreed to the largest settlement in DEA history at the time—$80 million—to resolve allegations that it committed an unprecedented number of recordkeeping and dispensing violations of the CSA, including negligently allowing controlled substances such as oxycodone and other prescription painkillers to be diverted for abuse and illegal black-market

sales. In addition to the monetary payment, the Jupiter, Florida distribution center lost its authority to distribute or dispense controlled substances, including opioids, for two years. The Department of Justice, in describing the settlement, explained that the conduct at issue included Walgreens's "alleged failure to sufficiently report suspicious orders was a systematic practice that resulted in at least tens of thousands of violations and allowed Walgreens's retail pharmacies to order and receive at least three times the Florida average for drugs such as oxycodone."[66]

428. The settlement resolved investigations into, and allegations of, CSA violations in Florida, New York, Michigan, and Colorado that resulted in the diversion of millions of opioids into illicit channels.

429. As part of the 2013 MOA described above, Walgreens "acknowledge[d] that certain Walgreens retail pharmacies did on some occasions dispense certain controlled substances in a manner not fully consistent with its compliance obligations under the CSA . . . and its implementing regulations." The 2013 MOA required Walgreens to, among other things, "maintain a compliance program in an effort to detect and prevent diversion of controlled substances" as required by law.

430. Walgreens's Florida operations at issue in this settlement highlight its egregious conduct regarding diversion of prescription opioids. Walgreens's Florida pharmacies each allegedly ordered more than one million dosage units of oxycodone in 2011—more than ten times the average amount.

[66] Press Release, U.S. Attorney's Office S. Dist. of Fla., *Walgreens Agrees To Pay A Record Settlement Of $80 Million For Civil Penalties Under The Controlled Substances Act*, U.S. Dep't of Just. (June 11, 2013), https://www.justice.gov/usao-sdfl/pr/walgreens-agrees-pay-record-settlement-80-million-civil-penalties-under-controlled.

431. They increased their orders over time, in some cases as much as 600% in the space of just two years, including, for example, supplying a town of 3,000 with 285,800 orders of oxycodone in a one-month period. Yet Walgreens corporate officers not only turned a blind eye, but provided pharmacists with incentives through a bonus program that compensated them based on the number of prescriptions filled at the pharmacy. Yet Walgreens corporate officers turned a blind eye to these abuses. In fact, the long term Controlled Substance Compliance Officer at Walgreens suggested, in reviewing the legitimacy of prescriptions coming from pain clinics, that "if these are legitimate indicators of inappropriate prescriptions perhaps we should consider not documenting our own potential noncompliance," underscoring Walgreens's attitude that profit outweighed compliance with the CSA or the health of communities.

432. Walgreens's settlement with the DEA stemmed from the DEA's investigation into Walgreens's distribution center in Jupiter, Florida, which was responsible for significant opioid diversion in Florida. According to the Order to Show Cause, Defendant Walgreens's corporate headquarters pushed to increase the number of oxycodone sales to Walgreens's Florida pharmacies, and provided bonuses for pharmacy employees based on number of prescriptions filled at the pharmacy in an effort to increase oxycodone sales. In July 2010, Defendant Walgreens ranked all of its Florida stores by number of oxycodone prescriptions dispensed in June of that year, and found that the highest-ranking store in oxycodone sales sold almost 18 oxycodone prescriptions per day. All of these prescriptions were filled by the Jupiter Center, a distribution center that also distributed into the City.

433. An August 2013 email shows Walgreens understood the consequences of its actions, explaining that Walgreens's "previous system would continue to send additional product

to the store without limit or review which made possible the runaway growth of dispensing products like Oxycodone."

434. Walgreens has also settled with a number of state attorneys general, including West Virginia ($575,000) and Massachusetts ($200,000).

435. The Massachusetts Attorney General's Medicaid Fraud Division found that, from 2010 through most of 2015, multiple Walgreens stores across the state failed to monitor the opioid use of some Medicaid patients who were considered high-risk.

436. In January 2017, an investigation by the Massachusetts Attorney General found that some Walgreens pharmacies failed to monitor patients' drug use patterns and didn't use sound professional judgment when dispensing opioids and other controlled substances—despite the context of soaring overdose deaths in Massachusetts. Walgreens agreed to pay $200,000 and follow certain procedures for dispensing opioids.

437. The actions against Walgreens as both a distributor and a retail pharmacy demonstrate it routinely, and as a matter of standard operating procedure, violated its legal obligations under the CSA and other laws and regulations governing the distribution and dispensing of prescription opioids.

2. Walmart

438. In addition to the actions described herein against Walmart, a prosecution against a Virginia prescriber revealed failures at Walmart pharmacies from 2007 to 2012. A Decision and Order in that case revealed that a Walmart pharmacy would fill prescriptions pursuant to a telephone message from a staff member of the prescriber, purportedly on behalf of the prescriber, even though she failed to provide the prescriber's DEA number. Despite the absence of

information required by DEA regulations, the Walmart pharmacy would fill the prescription.[67] By mid-November of 2008, three Walmart pharmacies had dispensed more than 200 hydrocodone prescriptions and refills on behalf of the prescriber. In 2012, the prescriber learned that someone was fraudulently using his DEA number. He called a Walmart pharmacy regarding refill requests faxed from his office, and advised "that somebody was fraudulently using [his] DEA number."[68] Although he asked that his DEA number be blocked, the same pharmacy still filled two prescriptions on his behalf after this alert. Although Walmart did not face sanctions for its conduct, the Opinion and Order described "the fact that prescriptions which were missing [the] Respondent's DEA number were routinely filling notwithstanding that they were facially invalid," and "that the prescriptions were for hydrocodone in quantities and dosings that were clearly outside the scope of what is usually prescribed by podiatrists" as "deeply disturbing."[69]

439. Federal prosecutors had also taken action against five Walmart and Sam's Club Pharmacies in Texas, alleging that they failed to keep records required to help prevent diversion of controlled substances as required by the CSA. Specifically, "accountability audits did not match the drugs on hand, revealing major overages and shortages in the accountability of controlled substances, and there were missing invoices for controlled substances all in violation of the CSA."[70] A U.S. Attorney further explained that "[b]ecause of the pharmacies' lack of proper

[67] DOJ, DEA, Docket No. 15-26, [FR Doc. No. 2017-13158] Peter F. Kelly, D.P.M.; Decision and Order, https://www.deadiversion.usdoj.gov/fed_regs/actions/2017/fr0623.htm.

[68] https://www.deadiversion.usdoj.gov/fed_regs/actions/2017/fr0623.htm

[69] *Id.*

[70] Associated Press, *Wal-Mart Settles Drug Records Accusation*, (Jan 7, 2009), http://prev.dailyherald.com/story/?id=262762

record keeping, a variety of Schedule II, III, IV and V controlled substances were lost or stolen and possibly diverted."[71]

440. As recently as September 2018, minutes of an Oklahoma State Board of Pharmacy meeting reflect that an Oklahoma "Wal-Mart Pharmacy was charged with multiple violations of state and federal regulations and rules including establishing and maintaining effective controls against diversion of prescription drugs."[72] Walmart agreed to pay a fine to resolve the seven alleged violations.

J. Defendants Conspired to Engage In The Wrongful Conduct Complained Of Herein and Intended To Benefit Both Independently and Jointly From Their Conspiracy

441. In addition, and on an even broader level, all Defendants took advantage of the industry structure, including end-running its internal checks and balances, to their collective advantage. Defendants agreed among themselves to increase the supply of opioids and fraudulently increase the quotas that governed the manufacture and supply of prescription opioids. Defendants did so to increase sales, revenue, and profit from their opioid products.

442. The interaction and length of the relationships between and among the Defendants reflects a deep level of interaction and cooperation between Defendants in a tightly knit industry. Defendants operated together as a united entity, working together on multiple fronts, to engage in the unlawful sale of prescription opioids.

443. Defendants collaborated to expand the opioid market in an interconnected and interrelated network in the following ways, as set forth more fully below, including, for example, membership in the NACDS.

---

[71] *Id.*

[72] https://www.ok.gov/pharmacy/documents/Min%20September%202018.pdf.

444. Defendants utilized their membership in the NACDS and other forms of collaboration to form agreements about their approach to their duties under the CSA to report suspicious orders. The Defendants overwhelmingly agreed on the same approach—to fail to identify, report or halt suspicious opioid orders, and fail to prevent diversion. Defendants' agreement to restrict reporting provided an added layer of insulation from DEA scrutiny for the entire industry as Defendants were thus collectively responsible for each other's compliance with their reporting obligations. Defendants were aware, both individually and collectively, of the suspicious orders that flowed directly from Defendants' facilities.

445. Defendants knew that their own conduct could be reported by other Defendants and that their failure to report suspicious orders they filled could be brought to the DEA's attention. As a result, Defendants had an incentive to communicate with each other about the reporting or suspicious orders to ensure consistency in their dealings with DEA.

446. The Defendants also worked together to ensure that the opioid quotas allowed by the DEA remained artificially high and ensured that suspicious orders were not reported to the DEA in order to ensure that the DEA had not basis for refusing to increase or decrease production quotas due to diversion.

447. The desired consistency, and collective end goal was achieved. Defendants achieved blockbuster profits through higher opioid sales by orchestrating the unimpeded flow of opioids.

K. Facts Pertaining to Claims Under the Racketeer Influenced and Corrupt Organizations ("RICO") Act

448. Additional facts pertaining to the RICO claims are set forth above in Sections 1.E and I.J.

449. Defendants' actions went far beyond what could be considered ordinary business conduct. For more than a decade, Walgreens and Walmart, the "RICO Supply Chain Defendants" worked with distributors Cardinal, McKesson, and AmerisourceBergen, along with manufacturers Purdue, Actavis, Cephalon, Endo, and Mallinckrodt in an illicit enterprise, engaging in conduct that was not only illegal, but in certain respects anti-competitive, with the common purpose and achievement of vastly increasing their respective profits and revenues by exponentially expanding a market that the law intended to restrict.

450. Knowing that dangerous drugs have a limited place in our society, and that their dissemination and use must be vigilantly monitored and policed to prevent the harm that drug abuse and addiction causes to individuals, society and governments, Congress enacted the Controlled Substances Act ("CSA"). Specifically, through the CSA, which created a closed system of distribution for controlled substances, Congress established an enterprise for good. The CSA imposes a reporting duty that cuts across company lines. Regulations adopted under the CSA require that companies who are entrusted with permission to operate with within this system cannot simply operate as competitive in an "anything goes" profit-maximizing market. Instead, the statute tasks them to watch over each other with a careful eye for suspicious activity. Driven by greed, Defendants betrayed that trust and subverted the constraints of the CSA's closed system to conduct their own enterprise for evil.

451. As "registrants" under the CSA, the RICO Supply Chain Defendants are duty bound to identify and report "orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency."[73]

[73] 21 C.F.R. 1301.74(b).

452. If morality and the law did not suffice, competition dictates that the Supply Chain Defendants would turn in their rivals when they had reason to suspect suspicious activity. Indeed, if a registrant could gain market share by reporting a competitor's illegal behavior (causing it to lose a license to operate, or otherwise inhibit its activity), ordinary business conduct dictates that it would do so. Unfortunately, however, that is not what happened. Instead, knowing that investigations into potential diversion would only lead to shrinking markets. The RICO Supply Chain Defendants elected to operate in a conspiracy of silence, in violation of both the CSA and RICO.

453. The RICO Supply Chain Defendants' scheme required the participation of all. If any one member broke rank, its compliance activities would highlight deficiencies of the others, and the artificially high quotas they maintained through their scheme would crumble. But, if all the members of the enterprise conducted themselves in the same manner, it would be difficult for the DEA to go after any one of them. The Supply Chain Defendants chose to flout the closed system designed to protect the citizens. Publicly, in 2008, the HDA, as described above, announced their formulation of "Industry Compliance Guidelines: Reporting Suspicious Orders and Prevention Diversion of Controlled Substances." But, privately, Defendants refused to act and through their lobbying efforts, they collectively sought to undermine the impact of the CSA. Indeed, despite the issuance of these Industry Compliance Guidelines, which recognize these Defendants' and the third-party members' of the enterprise's duties under the law, as illustrated by the subsequent industry-wide enforcement actions and consent orders issued after that time, none of them complied. John Gray, President and CEO of the HDA said to Congress in 2014, it is "difficult to find the right balance between proactive anti-diversion efforts while not inadvertently limiting access to appropriately prescribed and dispensed medications." Yet, the

Supply Chain Defendants apparently all found the same profit-maximizing balance -- intentionally remaining silent to ensure the largest possible financial return.

454. As described above, at all relevant times, the RICO Supply Chain Defendants operated as an association-in-fact enterprise formed for the purpose of unlawfully increasing sales, revenues, and profits by fraudulently increasing the quotas set by the DEA that would allow them to collectively benefit from a greater pool of prescription opioids to manufacture and distribute. In support of this common purpose and fraudulent scheme, the Defendants jointly agreed to disregard their statutory duties to identify, investigate, halt and report suspicious orders of opioids and diversion of their drugs into the illicit market so that those orders would not result in a decrease, or prevent an increase in, the necessary quotas and their profits.

455. At all relevant times, as described above, the RICO Supply Chain Defendants exerted control over, conducted and/or participated in the Opioid Supply Chain Enterprise by fraudulently claiming that they were complying with their duties under the CSA to identify, investigate and report suspicious orders of opioids in order to prevent diversion of those highly addictive substances into the illicit market, and to halt such unlawful sales, so as to increase production quotas and generate unlawful profits, as follows:

456. The RICO Supply Chain Defendants disseminated false and misleading statements to state and federal regulators claiming, among other things, that:

a. they were complying with their obligations to maintain effective controls against diversion of their prescription opioids;

b. they were complying with their obligation to notify the DEA of any suspicious orders or diversion of their prescription opioids; and

c. they did not have the capability to identify suspicious orders of controlled substances or were in the midst of a learning curve.

457. The Defendants applied political and other pressure on the DOJ and DEA to halt prosecutions for failure to report suspicious orders of prescription opioids and lobbied Congress to strip the DEA of its ability to immediately suspend registrations pending investigation by passing the "Ensuring Patient Access and Effective Drug Enforcement Act."[74]

458. The CSA and the Code of Federal Regulations require the Supply Chain Defendants to make reports to the DEA of any suspicious orders identified through the design and operation of their system to disclose suspicious orders. The failure to make reports as required by the CSA and Code of Federal Regulations amounts to a criminal violation of the statute.

459. The RICO Supply Chain Defendants knowingly and intentionally furnished false or fraudulent information in their reports to the DEA about suspicious orders, and/or omitted material information from reports, records and other documents required to be filed with the DEA, including the Marketing Defendants' applications for production quotas. Specifically, the RICO Supply Chain Defendants were aware of suspicious orders of prescription opioids and the diversion of their prescription opioids into the illicit market and failed to report this information to the DEA in the manufacturers' mandatory reports and their applications for production quotas.

---

[74] *See HDMA is now the Healthcare Distribution Alliance*, Pharmaceutical Commerce, (June 13, 2016, updated July 6, 2016), http://pharmaceuticalcommerce.com/business-and-finance/hdma-now-healthcare-distribution-alliance/; Lenny Bernstein & Scott Higham, *Investigation: The DEA Slowed Enforcement While the Opioid Epidemic Grew Out of Control*, Wash. Post, Oct. 22, 2016, https://www.washingtonpost.com/investigations/the-dea-slowed-enforcement-while-the-opioid-epidemic-grew-out-of-control/2016/10/22/aea2bf8e-7f71-11e6-8d13-d7c704ef9fd9_story.html; Lenny Bernstein & Scott Higham, *Investigation: U.S. Senator Calls for Investigation of DEA Enforcement Slowdown Amid Opioid Crisis*, Wash. Post, Mar. 6, 2017, https://www.washingtonpost.com/investigations/us-senator-calls-for-investigation-of-dea-enforcement-slowdown/2017/03/06/5846ee60-028b-11e7-b1e9-a05d3c21f7cf_story.html; Eric Eyre, *DEA Agent: "We Had no Leadership" in WV Amid Flood of Pain Pills*, Charleston Gazette-Mail, Feb. 18, 2017, http://www.wvgazettemail.com/news/20170218/dea-agent-we-had-no-leadership-in-wv-amid-flood-of-pain-pills-.

460. The RICO Supply Chain Defendants used, directed the use of, and/or caused to be used, thousands of interstate mail and wire communications in service of their scheme through virtually uniform misrepresentations, concealments and material omissions regarding their compliance with their mandatory reporting requirements and the actions necessary to carry out their unlawful goal of selling prescription opioids without reporting suspicious orders or the diversion of opioids into the illicit market.

461. In devising and executing the illegal scheme, the RICO Supply Chain Defendants devised and knowingly carried out a material scheme and/or artifice to defraud by means of materially false or fraudulent pretenses, representations, promises, or omissions of material facts.

462. For the purpose of executing the illegal scheme, the RICO Supply Chain Defendants committed incidents of corrupt activity, which number in the thousands, intentionally and knowingly with the specific intent to advance the illegal scheme. These incidents of corrupt activity, which included repeated acts of mail fraud, wire fraud, and telecommunications fraud, constituted a pattern of racketeering.

463. The RICO Supply Chain Defendants' use of the mail and wires includes, but is not limited to, the transmission, delivery, or shipment of the following by the Marketing Defendants, the distributors, or third parties that were foreseeably caused to be sent as a result of the RICO Supply Chain Defendants' illegal scheme, including, but not limited to:

a. The prescription opioids themselves;

b. Documents and communications that supported and/or facilitated the RICO Supply Chain Defendants' request for higher aggregate production quotas, individual production quotas, and procurement quotas;

c. Documents and communications that facilitated the manufacture, purchase and sale of prescription opioids;

d. RICO Supply Chain Defendants' DEA registrations;

e. Documents and communications that supported and/or facilitated RICO Supply Chain Defendants' DEA registrations;

f. RICO Supply Chain Defendants' records and reports that were required to be submitted to the DEA pursuant to 21 U.S.C. § 827;

g. Documents and communications related to the RICO Supply Chain Defendants' mandatory DEA reports pursuant to 21 U.S.C. § 823 and 21 C.F.R. § 1301.74;

h. Documents intended to facilitate the manufacture and distribution of the RICO Supply Chain Defendants' prescription opioids, including bills of lading, invoices, shipping records, reports and correspondence;

i. Documents for processing and receiving payment for prescription opioids;

j. Payments from the Distributors to the Marketing Defendants;

k. Rebates and chargebacks from the Marketing Defendants to the distributors;

l. Payments to the RICO Supply Chain Defendants' lobbyists through the PCF;

m. Payments to the RICO Supply Chain Defendants' trade organizations, like the HDA, for memberships and/or sponsorships;

n. Deposits of proceeds from the RICO Supply Chain Defendants' manufacture and distribution of prescription opioids; and

o. Other documents and things, including electronic communications.

464. The RICO Supply Chain Defendants (and/or their agents), for the purpose of executing the illegal scheme, sent and/or received (or caused to be sent and/or received) by mail or by private or interstate carrier, shipments of prescription opioids and related documents by mail or by private carrier affecting interstate commerce.

465. Each of the RICO Supply Chain Defendants identified shipped, paid for and received payment for the drugs identified above, throughout the United States.

466. The RICO Supply Chain Defendants used the internet and other electronic facilities to carry out their scheme and conceal the ongoing fraudulent activities. Specifically, the Supply Chain Defendants made misrepresentations about their compliance with Federal and State laws requiring them to identify, investigate and report suspicious orders of prescription opioids and/or diversion of the same into the illicit market.

467. At the same time, the RICO Supply Chain Defendants misrepresented the superior safety features of their order monitoring programs, ability to detect suspicious orders, commitment to preventing diversion of prescription opioids, and their compliance with all state and federal regulations regarding the identification and reporting of suspicious orders of prescription opioids.

468. The RICO Supply Chain Defendants utilized the internet and other electronic resources to exchange communications, to exchange information regarding prescription opioid sales, and to transmit payments and rebates/chargebacks.

469. The RICO Supply Chain Defendants also communicated by U.S. Mail, by interstate facsimile, and by interstate electronic mail with each other and with various other affiliates, regional offices, regulators, distributors, and other third-party entities in furtherance of the scheme.

470. The mail and wire transmissions described herein were made in furtherance of the RICO Supply Chain Defendants' scheme and common course of conduct to deceive regulators, the public and the Plaintiffs that these Defendants were complying with their state and federal obligations to identify and report suspicious orders of prescription opioids all while Defendants and the Enterprise members were knowingly allowing millions of doses of prescription opioids to divert into the illicit drug market. The Supply Chain Defendants' scheme and common course of conduct was to increase or maintain high production quotas for their prescription opioids from which they could profit.

471. Many of the precise dates of the fraudulent uses of the U.S. mail and interstate wire facilities have been deliberately hidden by Defendants and cannot be alleged without access to Defendants' books and records. However, the City has described the types of, and in some instances, occasions on which the predicate acts of mail and/or wire fraud occurred. They include thousands of communications to perpetuate and maintain the scheme, including the things and documents described in the preceding paragraphs.

472. The Supply Chain Defendants did not undertake the practices described herein in isolation, but as part of a common scheme. Various other persons, firms, and corporations, including third-party entities and individuals not named as defendants in this Complaint, may have contributed to and/or participated in the scheme with these Defendants in these offenses and have performed acts in furtherance of the scheme to increase revenues, increase market share, and /or minimize the losses for the RICO Supply Chain Defendants.

473. The predicate acts constituted a variety of unlawful activities, each conducted with the common purpose of obtaining significant monies and revenues from the sale of their highly addictive and dangerous drugs. The predicate acts also had the same or similar results, participants, victims, and methods of commission. The predicate acts were related and not isolated events.

474. The predicate acts all had the purpose of creating the opioid epidemic that substantially injured the City's business and property, while simultaneously generating billion-dollar revenue and profits for the RICO Supply Chain Defendants. The predicate acts were committed or caused to be committed by the Defendants through their participation in the Opioid Supply Chain Enterprise and in furtherance of its fraudulent scheme.

475. As described above, the RICO Supply Chain Defendants were repeatedly warned, fined, and found to be in violation of applicable law and regulations, and yet they persisted. The

sheer volume of enforcement actions against the RICO Supply Chain Defendants supports this conclusion that the RICO Supply Chain Defendants operated through a pattern and practice of willfully and intentionally omitting information from their mandatory reports to the DEA as required by 21 C.F.R. § 1301.74.[75]

476. Each instance of corrupt activity alleged herein was related, had similar purposes, involved the same or similar participants and methods of commission, and had similar results affecting similar victims, the City, and its residents. The RICO Supply Chain Defendants calculated and intentionally crafted the diversion scheme to increase and maintain profits from unlawful sales of opioids, without regard to the effect such behavior would have on the City and its residents. The Supply Chain Defendants were aware that the City and its residents rely on these Defendants to maintain a closed system of distribution to protect against the non-medical diversion and use of their dangerously addictive opioid drugs.

477. By intentionally refusing to report and halt suspicious orders of their prescription opioids, the Supply Chain Defendants engaged in a fraudulent scheme and unlawful course of conduct constituting a pattern of racketeering activity.

II. Florida-Specific Facts

A. Defendants Breached Their Duties in Florida and the City.

478. The Chain Pharmacies all distributed and dispensed opioids in Florida and failed to meet their regulatory and common law obligations while doing so.

[75] Evaluation and Inspections Div., Office of the Inspector Gen., U.S. Dep't of Justice, *The Drug Enforcement Administration's Adjudication of Registrant Actions* 6 (2014), https://oig.justice.gov/reports/2014/e1403.pdf.

479. Florida law requires distributors to comply with applicable federal requirements (including those set forth in the Controlled Substances Act and its implementing regulations.) *See* Fla. Stat. Ann. § 499.0121.

480. In addition to the duties imposed by federal law, under Florida law, each distributor must conduct due diligence of purchasers. *See* Fla. Stat. Ann. § 499.0121(15). This includes an obligation to "take reasonable measures to identify its customers, understand the normal and expected transactions conducted by those customers, and identify those transactions that are suspicious in nature." Fla. Stat. Ann. § 499.0121(15)(b). "A wholesale distributor must establish internal policies and procedures for identifying suspicious orders and preventing suspicious transactions." *Id.* Further, "[a] wholesale distributor must assess orders for more than 7,500 unit doses of any one controlled substance in any one month to determine whether the purchase is reasonable," and in so doing "may consider the purchasing entity's clinical business needs, location, and population served, in addition to other factors established in the distributor's policies and procedures." *Id.* "A wholesale distributor must report . . . any regulated transaction involving an extraordinary quantity of a listed chemical, an uncommon method of payment or delivery, or any other circumstance that the regulated person believes may indicate that the listed chemical will be used in violation of the law" and "maintain records that document the report submitted . . . ." *Id.*

481. The Florida Pharmacy Act, set forth in Chapter 465, imposes obligations on dispensing pharmacies. Under Fla. Stat. Ann. § 465.015:

> It is unlawful for any pharmacist to knowingly fail to report to the sheriff or other chief law enforcement agency of the county where the pharmacy is located within 24 hours after learning of any instance in which a person obtained or attempted to obtain a controlled substance, as defined in s. 893.02, or at the close of business on the next business day, whichever is later, that the pharmacist knew or believed was

> obtained or attempted to be obtained through fraudulent methods or representations from the pharmacy at which the pharmacist practiced pharmacy.

Fla. Stat. Ann. § 465.015(3). The Act requires "policies and procedures for preventing controlled substance dispensing based on fraudulent representations or invalid practitioner-patient relationships," Fla. Stat. Ann. § 465.022, and underscores the importance of ensuring controlled substances prescriptions are valid before dispensing. Indeed, the Florida Board of Pharmacy may deny a pharmacy or pharmacist a license or commence disciplinary action based on conduct in "dispensing . . . any controlled substance, other than in the course of the professional practice of pharmacy." Fla. Stat. Ann. § 465.016(1)(i) (further stating that "[f]or purposes of this paragraph, it shall be legally presumed that the compounding, dispensing, or distributing of legend drugs in excessive or inappropriate quantities is not in the best interests of the patient and is not in the course of the professional practice of pharmacy").

482. Further, under the Florida Comprehensive Drug Abuse Prevention and Control Act, "[a] pharmacist may not dispense a controlled substance listed in Schedule II, Schedule III, or Schedule IV to any patient or patient's agent without first determining, in the exercise of her or his professional judgment, that the prescription is valid." Fla. Stat. 893.04(2)(a).

483. As noted above, apart from Florida and federal statutes, Defendants have a duty to exercise reasonable care when selling, distributing, and dispensing opioids.

484. Although they act through their agents, the Chain Pharmacies, as the registrants, are ultimately responsible to prevent diversion, as described above.

485. Thus, in addition to their duties as distributors, the Chain Pharmacies also had a duty to design and implement systems to prevent diversion of controlled substances in their retail pharmacy operations. The Chain Pharmacies had the ability, and the obligation, to look for these

red flags on a patient, prescriber, and store level, and to refuse to fill and to report prescriptions that suggested potential diversion.

486. The Chain Pharmacies knew, or should have known, that their pharmacies in Florida and the City, were (a) filling multiple prescriptions to the same patient using the same doctor; (b) filling multiple prescriptions by the same patient using different doctors; (c) filling prescriptions of unusual size and frequency for the same patient; (d) filling prescriptions of unusual size and frequency from out-of-state patients; (e) filling an unusual or disproportionate number of prescriptions paid for in cash; (f) filling prescriptions paired with other drugs frequently abused with opioids, like benzodiazepines, or prescription "cocktails"; (g) filling prescriptions in volumes, doses, or combinations that suggested that the prescriptions were likely being diverted or were not issued for a legitimate medical purpose; and (h) filling prescriptions for patients and doctors in combinations that were indicative of diversion and abuse. The Chain Pharmacies had the ability, and the obligation, to look for these red flags on a patient, prescriber, and store level, and to refuse to fill and to report prescriptions that suggested potential diversion.

487. The Chain Pharmacies either were on notice, or should have been on notice, that the diversion of opioids was likely occurring in Florida communities, should have investigated, ceased filling orders for opioids, and reported potential diversion.

488. In addition, the increase in fatal overdoses from prescription opioids has been widely publicized for years. Florida, and the area surrounding the City, have been hard hit by the opioid epidemic, and described above, and has faced a spike in fatal drug overdoses attributable to prescription opioids or the illicit opioids that patients often began abusing after becoming addicted to prescription opioids. The CDC estimates that for every opioid-related death, there are 733 non-

medical users. The Chain Pharmacies thus had every reason to believe that illegal diversion was occurring in the City.

489. The Chain Pharmacies had information about suspicious orders that they did not report, and also failed to exercise due diligence before filling orders from which drugs were diverted into illicit uses in communities across Florida.

490. Each of the Chain Pharmacies disregarded their reporting and due diligence obligations under federal law and Florida law. Instead, they consistently failed to report or suspend suspicious orders, deepening the crisis of opioid abuse, addiction, and death in Florida.

491. Each of the Chain Pharmacies participated in growing the market for prescription opioids in the United States and in Florida far beyond reasonable limits, and fueling the improperly expanded market with opioids.

B. The Chain Pharmacies Have Created and Maintained a Public Health Crisis in the City.

492. As discussed above, Sarasota County, in which the City sits, had an opioid prescription rate exceeding the national average for many years. Sarasota County's rate was higher even than state averages during a crucial time frame in which the epidemic unfolded.

493. There is a "parallel relationship between the availability of prescription opioid analgesics through legitimate pharmacy channels and the diversion and abuse of these drugs and associated adverse outcomes."[76] The opioid epidemic is "directly related to the increasingly widespread misuse of powerful opioid pain medications."[77]

[76] Dart, MD, et al., *Trends in Opioid Analgesic Abuse and Mortality in the United States,* New Engl. J. Med., 372:241-248 (January 15, 2015).
[77] Califf, MD, et al., *A Proactive Response to Prescription Opioid Abuse,* New Engl. J. Med. (April 14, 2016).

494. The volume of opioids distributed and sold in the City is so high as to raise a red flag that not all of the prescriptions being ordered and sold could be for legitimate medical uses.

495. By helping to improperly inflate the opioid market, continuing to fill and failing to report suspicious orders of opioids, and by continuing to dispense opioids and "cocktails" of opioids and other drug despite indicia of diversion, the Chain Pharmacies have contributed to an oversupply of opioids in Florida generally, and in the City specifically. This oversupply allowed non-patients to become exposed to opioids, and facilitated access to opioids for both patients who could no longer access or afford prescription opioids and individuals struggling with addiction and relapse. The Chain Pharmacies had financial incentives to sell higher volumes of opioids and not to report suspicious orders or guard against diversion, and to dispense opioids despite indicia of diversion.

496. According to the CDC, drug overdose deaths in Florida increased by 4.8% from 2013 to 2014, and by 22.7% from 2014 to 2015, with deaths increasing from 2,474, to 2,634, to 3,228 over the three-year period, with opioids being the main driver of those deaths. During that timeframe, drug overdose deaths in Florida increased from approximately 12 per 100,000 to 16 per 100,000. Further, the Florida Medical Examiners Commission's 2016 Interim Report indicates that between January and June 2016, 33.8% of decedents examined had opioids in their system at the time of death.

497. Sarasota has seen a corresponding rise in area opioid usage and accidental deaths. The Sarasota County Sheriff's office responded to 185 opioid-related calls with 32 deaths from January to July 2017 alone. As such, Sarasota was the first law enforcement agency in Florida to

equip its deputies with Naxolone, an epipen-like injector which is intended to keep people from overdosing as a result of opioid usage.[78] Sarasota's EMS personnel already carried the treatment.

498. Moreover, data from the CDC shows that drug overdose deaths have increased significantly during the COVID-19 pandemic. A study by the Scientific Committee on Opioid Prevention and Education also reported an alarming surge in the number of lives lost to opioid overdoses in 2020, with a three-month period described as the deadliest since the opioid epidemic began.

499. Sarasota, and Florida, were no exception. Reportedly, the Sarasota County Sheriff's Office responded to 29 opioid fatalities during the first half of 2020 alone.[79]

500. Additionally, the effects of the opioid epidemic spread beyond overdose-related deaths. An increase in Hepatitis C, according to the CDC, is directly tied to intravenous injection of opioids.

501. Children have borne the costs of opioid use and abuse. According to a State Department of Children and Families' report, Sarasota County has the second highest child-removal rate in the state, and opioid abuse is the number one reason for child removal. Specifically, County data demonstrates that 65% of child home removals are due to prescription drug abuse in the family. An average of 21 children are removed and placed into foster care within the County each month.[80]

---

[78] Topher Forhecz, *Sarasota Sheriff's Office Fiat Law Enforcement Agency in Florida to Give Deputies Naloxone*, WGCU News (Oct. 9, 2015), https://wusfnews.wusf.usf.edu/2015-10-09/sarasota-sheriffs-office-first-law-enforcement-agency-in-florida-to-give-deputies-naloxone

[79] Kelsey Sunderland, Opioid Deaths Surge in Sarasota and Manatee Counties, WFLA (July 7, 2020), Opioid deaths surge in Sarasota and Manatee counties | WFLA

[80] https://www.gulfcoastcf.org/our-initiatives/health-human-services/opioid-crisis-response

502. Even infants have not been immune to the impact of opioid abuse. There has been a dramatic rise in the number of infants who are born addicted to opioids due to prenatal exposure and suffer from neonatal abstinence syndrome ("NAS," also known as neonatal opioid withdrawal syndrome, or "NOWS"). These infants painfully withdraw from the drug once they are born, cry nonstop from the pain and stress of withdrawal, experience convulsions or tremors, have difficulty sleeping and feeding, and suffer from diarrhea, vomiting, and low weight gain, among other serious symptoms. The long-term developmental effects are still unknown, though research in other states has indicated that these children are likely to suffer from continued, serious neurologic and cognitive impacts, including hyperactivity, attention deficit disorder, lack of impulse control, and a higher risk of future addiction. When untreated, NAS can be life-threatening. In 2009, more than 13,000 infants in the United States were born with NAS, or about one every hour.

503. According to Florida's Agency for Health Care Administration, 1,903 infants at Florida hospitals suffered from neonatal abstinence syndrome in 2014.[81] That number climbed to 2,487 in 2015 and 4,215 in 2016.[82] At Sarasota Memorial Hospital, babies suffering from opioid addiction withdrawal numbered 67 in 2014, jumped to 110 in 2015, and peaked at 114 in 2016.[83] According to one nurse at the hospital, she would expect to see at least one baby with NAS each day.[84] The

[81] Dale White, *Neonatal opioid addiction cases spiked in Florida in 2016*, Sarasota Herald-Tribune (Jan. 25, 2018), https://www.heraldtribune.com/story/news/local/manatee/2018/01/25/neonatal-opioid-addiction-cases-spiked-in-florida-in-2016/15637321007/

[82] *Id.*

[83] *Id.*

[84] Hannah Morse, *The Tiniest Victims of* Heroin, Bradenton Herald (sept. 24, 2016), http://www.bradenton.com/news/local/heroin-epidemic/article103778121.html

average cost for a newborn in Sarasota is $4,322, but can rise to $23,372 for one dependent on opioids.[85]

504. Rising opioid use and abuse have negative social and economic consequences in other respects as well. According to a recent analysis by a Princeton University economist, approximately one out of every three working age men who are not in the labor force take daily prescription pain medication. The same research finds that opioid prescribing alone accounts for 20% of the overall decline in the labor force participation for this group from 2014-16, and 25% of the decline in labor force participation among women. Many of those taking painkillers still said they experienced pain daily.

505. People who are addicted to prescription opioid painkillers are 40 times more likely to be addicted to heroin. The CDC identified addiction to prescription pain medication as the strongest risk factor for heroin addiction. A recent, even more deadly problem stemming from the prescription opioid epidemic involves fentanyl—a powerful opioid carefully prescribed for cancer pain or in hospital settings that, in synthetic form, has made its way into Florida communities. There were 52 fentanyl-related deaths in Sarasota County in 2016.[86]

506. Sarasota continues to suffer significant damage as a result of opioid over- prescription and addiction, including, but not limited to, increased law enforcement and public works expenditures, increased expenditures for overtime, the hiring of additional City employees, mental health treatment and workers' compensation for its employees, increased emergency and treatment services, damage to

[85] Dale White, *Neonatal opioid addiction cases spiked in Florida in 2016*, Sarasota Herald-Tribune (Jan. 25, 2018), https://www.heraldtribune.com/story/news/local/manatee/2018/01/25/neonatal-opioid-addiction-cases-spiked-in-florida-in-2016/15637321007/.

[86] https://www.fdle.state.fl.us/MEC/Publications-and-Forms/Documents/Drugs-in-Deceased-Persons/2016-Annual-Drug-Report.aspx.

emergency equipment and vehicles, and lost productivity, economic opportunity, and tax revenue. In order to properly address this unprecedented epidemic and protect the safety and welfare of its residents, the City has had to significantly modify its emergency response plan, requiring the hiring of additional permanent emergency response personnel, overtime pay, and the purchase and maintenance of additional emergency vehicles and supplies, such as Naloxone[87] — none of which would otherwise have been necessary. Additionally, Sarasota must now pay to provide mental health services to its employees, who are on the front lines of assisting residents and visitors, and otherwise re-allocate City funds to cope with the opioid epidemic.

507. Sarasota, acting on its own behalf and on behalf of its residents, suffered both injuries and pecuniary losses proximately caused by Defendants' breaches. Among other things, and upon information and belief, Sarasota has experienced an unprecedented opioid addiction and overdose epidemic costing millions of dollars in increased law enforcement and public works expenditures, increased expenditures for overtime, the hiring of additional City employees, mental health treatment and workers' compensation for its employees, increased emergency and treatment services, damage to emergency equipment and vehicles, and lost productivity, economic opportunity, and tax revenue.

508. Fully addressing the crisis requires that those responsible for it pay for their conduct and to abate the nuisance and harms they have created in the City.

III. Statutes Of Limitations Are Tolled and Defendants Are Estopped From Asserting Statutes Of Limitations As Defenses.

A. Continuing Conduct

509. The City continues to suffer harm from the unlawful actions by the Defendants.

[87] Topher Forhecz, *Sarasota Sheriff's Office Fiat Law Enforcement Agency in Florida to Give Deputies Naloxone*, WGCU News (Oct. 9, 2015), https://wusfnews.wusf.usf.edu/2015-10-09/sarasota-sheriffs-office-first-law-enforcement-agency-in-florida-to-give-deputies-naloxone

510. The continued tortious and unlawful conduct by the Chain Pharmacies causes a repeated or continuous injury. The damages have not occurred all at once but have continued to occur and have increased as time progresses. The tort is not completed nor have all the damages been incurred until the wrongdoing ceases. The wrongdoing and unlawful activity by the Chain Pharmacies has not ceased. The public nuisance remains unabated. The conduct causing the damages remains unabated.

B. Equitable Estoppel and Fraudulent Concealment

511. The Chain Pharmacies are also equitably estopped from relying upon a statute of limitations defense because they undertook active efforts to deceive the City and to purposefully conceal their unlawful conduct and fraudulently assure the public, including the City, that they were undertaking efforts to comply with their obligations under the state and federal controlled substances laws, all with the goal of protecting their registered distributor and/or dispenser status and to continue generating profits. Notwithstanding the allegations set forth above, the Chain Pharmacies affirmatively assured the public, including the City, that they are working to curb the opioid epidemic.

512. The Chain Pharmacies were deliberate in taking steps to conceal their conspiratorial behavior and active role in the deceptive marketing and the oversupply of opioids through overprescribing and suspicious sales, all of which fueled the opioid epidemic.

513. The Chain Pharmacies also concealed from the City the existence of the City's claims by hiding their lack of cooperation with law enforcement and affirmatively seeking to convince the public that their legal duties to report suspicious sales had been satisfied through public assurances that they were working to curb the opioid epidemic. They publicly portrayed themselves as committed to working diligently with law enforcement and others to prevent diversion of these dangerous drugs and curb the opioid epidemic, and they made broad promises

to change their ways insisting they were good corporate citizens. These repeated misrepresentations misled regulators, prescribers and the public, including the City, and deprived the City of actual or implied knowledge of facts sufficient to put the City on notice of potential claims.

514. The City did not discover the nature, scope and magnitude of the Chain Pharmacies' misconduct, and its full impact on the City, and could not have acquired such knowledge earlier through the exercise of reasonable diligence.

515. The Chain Pharmacies intended that their actions and omissions would be relied upon, including by the City. The City did not know and did not have the means to know the truth, due to the Chain Pharmacies' actions and omissions.

516. The City reasonably relied on the Chain Pharmacies' affirmative statements regarding their purported compliance with their obligations under the law.

CAUSES OF ACTION

COUNT I
Public Nuisance
(Against All Defendants)

517. The City incorporates the allegations within all prior paragraphs within this Complaint as if they were fully set forth herein.

801. Defendants, individually and acting through their employees and agents, and in concert with each other, have intentionally, recklessly, or negligently engaged in conduct or omissions which endanger or injure the property, health, safety or comfort of the public in Sarasota. Defendants have created and maintained a public nuisance through their ongoing conduct of distributing, dispensing, and selling opioids, which are dangerously addictive drugs, in a manner which caused prescriptions and sales of opioids to skyrocket in Plaintiff's community, flooded Plaintiff's community with opioids, and facilitated and encouraged the flow and diversion of

opioids into an illegal, secondary market, resulting in devastating consequences to Plaintiff and the residents of Plaintiff's community.

518. Defendants unreasonably interfered with rights common to the general public within the City by failing to design and operate a system that would disclose the existence of suspicious orders of controlled substances and/or by failing to report and reject suspicious orders of opioids and failing to maintain effective controls against diversion, including from their retail stores, as required by Florida law and the federal CSA.

519. In addition, Defendants intentionally and unreasonably, unlawfully, and/or negligently collaborated in deceptive marketing of opioids, acting in concert with opioid manufacturers to promote the false messaging about the treatment of pain and the addictive nature of opioids, to encourage their use by health care providers and patients, and to encourage their pharmacists to fill as many opioid prescriptions as possible in the face of indicia of diversion. The Chain Pharmacies worked in concert with opioid manufacturers and distributors to ensure that the false messaging surrounding the treatment of pain and the addictive nature of opioids was consistent and geared to increase profits for all stakeholders. The Chain Pharmacies invited manufacturers to train and provide messaging to the Chain Pharmacies' pharmacists to ensure that those pharmacists would continue to fill as many prescriptions as possible despite indicia of diversion.

520. Since their inception, Florida laws, which are no less stringent than the federal CSA, have been designed to prevent precisely the type of harm that Defendants caused. Defendants' statutory obligations are key to maintaining a "closed" system intended to reduce the diversion of drugs dangerous enough to be regulate as controlled substances outside of legitimate

channels and into the illicit market, while at the same time providing the legitimate drug industry with a unified approach to narcotic and dangerous drug control.[88]

521. In light of Defendants' failures to disclose suspicious orders of opioids and maintain adequate controls to prevent diversion, the City was unaware of, and could not reasonably know or have learned through reasonable diligence, that it had been exposed to the risks alleged herein. Information pertaining to the suspicious orders of opioids Defendants were required to disclose—but did not—was information that the Defendants, given their placement in the supply chain, are uniquely positioned to possess and which was otherwise unavailable to the City. At all times relevant to this Complaint, Defendants were in complete control over the instrumentalities constituting the public nuisance.

522. Further, Defendants misleadingly portrayed themselves as cooperating with law enforcement and actively working to combat the opioid epidemic when, in reality, Defendants failed to satisfy even their minimum, legally-required obligations to report suspicious prescribers.

802. Defendants' unlawful, intentional, negligent, and/or unreasonable nuisance-creating conduct, includes:

a. Distributing, dispensing, and selling opioids in ways that facilitated and encouraged their flow into the illegal, secondary market;

b. Distributing and dispensing, opioids without maintaining effective controls against the diversion of opioids;

c. Choosing not to and/or negligently failing to effectively monitor for suspicious orders;

d. Choosing not to and/or negligently failing to investigate suspicious orders;

e. Choosing not to and/or negligently failing to report suspicious orders;

f. Choosing not to stop or suspend shipments of suspicious orders;

[88] *See* 1970 U.S.C.C.A.N. 4566, 4571-72.

g. Distributing, dispensing, and selling opioids prescribed by "pill mills" when Defendants knew or should have known the opioids were being prescribed by "pill mills;"

h. Failing to use the data available to them to identify suspicious orders, suspicious red flag prescriptions, and to otherwise prevent or reduce the risk of diversion; and

i. Acting in concert with opioid manufacturers to promote the false messaging about the treatment of pain and the addictive nature of opioids, to encourage their use by health care providers and patients, and to encourage their pharmacists to fill as many opioid prescriptions as possible in the face of indicia of diversion.

523. Defendants have created or assisted in the creation of a condition that is injurious to public health, public safety, public peace, and public comfort and offends the moral standards of the community.

524. Defendants' acts and omissions offend, significantly and unreasonably interfere with, and cause damage to the public rights common to all, such as the public health, public safety, public peace, and the public comfort. Defendants had control over their conduct in the City and that conduct has had an adverse effect on the public right. The public nuisance caused by Defendants has significantly harmed the City and a considerable number of City residents.

525. Defendants' conduct is not insubstantial or fleeting. It has caused deaths, serious injuries, and a severe disruption of public peace, health, order and safety; it is ongoing, and it is producing permanent and long-lasting damage.

526. Defendants' conduct is unreasonable intentional, and unlawful.

527. Defendants knew and should have known that their unlawful, unfair, and fraudulent actions would create or assist in the creation of the public nuisance.

528. Defendants intentionally, recklessly, or negligently engaged in conduct proscribed by statute, ordinance or administrative regulation, as described in this Complaint, including violations of the Florida Comprehensive Drug Abuse Prevention and Control Act, Fla. Stat. Ann.

§ 893.01 *et seq.*, and Florida Deceptive and Unfair Trade Practices Act, Fla. Stat. Ann. §501.201-501.207, and the Florida Pharmacy Act, Fla. Stat. Ann. § 465.001 *et seq.*, which require that distributors and pharmacies satisfy registration and licensing requirements mandating that they "maintain effective controls against diversion of controlled substances into other than legitimate medical, scientific, or industrial channels" and comply with "applicable federal, state, and local law," including the mandates of the federal Controlled Substances Act set forth in 21 U.S.C. § 823 and 21 C.F.R. 1301.74 and with the Florida laws described in this Complaint.

803. Defendants owed the public legal duties, including:

a. a preexisting duty not to expose the City and its residents to an unreasonable risk of harm;

b. a duty to exercise reasonable and ordinary care and skill in accordance with applicable standards of conduct in marketing, selling, dispensing, and/or distributing opioids; and

c. a duty not to breach the standard of care established under Florida laws and the federal Controlled Substances Act ("CSA") and their respective implementing regulations to report suspicious prescribing and to maintain systems to detect and report such activity.

804. As evidence of addiction and abuse of opioids widened, Defendants were obligated to rein in their supply, prevent diversion, and mitigate the harms from opioid overuse and abuse, but intentionally and unreasonably and/or negligently failed to do so.

529. The degree of care the law requires is commensurate with the risk of harm the conduct creates. Defendants' conduct in distributing, dispensing, and selling dangerously addictive drugs requires a high degree of care and places them in a position of great trust and responsibility. Their duty cannot be delegated.

530. The public nuisance is substantial and unreasonable. Defendants' actions caused and continue to cause the public health epidemic described in the Complaint.

531. Defendants had control over their acts and omissions, the instrumentalities causing the public nuisance, at the time the damage occurred. All Defendants had control over their own shipments and sales of opioids and over their reporting, or lack thereof, of suspicious prescribers and orders. Each of the Defendants controlled the systems it developed to control against diversion, including the criteria and process used to identify red flags of suspicious orders or prescribing.

532. Defendants also controlled whether and to what extent they trained their employees to report and exercise due diligence not to fill such orders or supply such prescribers, whether they intentionally manipulated their systems or ordering process to avoid reporting red flags or declining shipments, and whether they filled orders they knew or should have known were likely to be diverted or fuel an illegal market.

533. All Defendants' actions were, at the very least, a substantial factor in opioids becoming widely available and widely used in the City. Defendants controlled these actions and, therefore, willingly participated to a substantial extent in creating and maintaining the public nuisance. Without Defendants' actions, opioid use, misuse, abuse, and addiction would not have become so widespread, and the opioid epidemic that now exists would have been averted or much less severe. Defendants' conduct alleged in this Complaint exacerbated the opioid crisis in the City, and failed to limit its reach.

534. Defendants' conduct directly and proximately caused injury to Plaintiff and its residents.

535. It was reasonably foreseeable that Defendants' actions and omissions would result in the public nuisance and harm to Plaintiff described herein.

536. The City suffered special injuries distinguishable from those suffered by the general public. As discussed herein, it has incurred substantial costs from investigating, monitoring, treating, policing, and remediating the opioid epidemic. The City's damages are not merely derivative of harm to third parties.

537. The public nuisance created, perpetuated, and maintained by Defendants can be abated and further recurrence of such harm and inconvenience can be abated. Defendants have the ability to act to abate the public nuisance, and in certain respects, the law recognizes that they are uniquely well positioned to do so.

538. Defendants are also uniquely well-positioned to stop fueling, and to cut off at the source, diversion of prescription opioids. As registered distributors and dispensers of controlled substances, Defendants are placed in a position of special trust and responsibility. Because of their direct relationship with customers in the supply chain, they are uniquely capable of identifying red flags of diversion and guarding against the movement of legal pharmaceutical controlled substances from legitimate channels into the illicit market. Their obligation to maintain effective controls to prevent diversion of controlled substances is critical.

539. The misconduct alleged in this case does not concern a discrete event or discrete emergency of the sort a political subdivision would reasonably expect to occur, and is not part of the normal and expected costs of a local government's existence.

WHEREFORE, The City demands judgment in its favor against the Defendants for compensatory damages in an amount to be determined by a jury, abatement of the public nuisance, and injunctive relief together with all the costs of this action, including prejudgment interest, post-judgment interest, costs and expenses, attorney fees, and such other relief as this Court deems just and equitable.

COUNT II
Florida Deceptive and Unfair Trade Practices Act
Fla. Stat. Ann. §501.201- 501.207
(Against All Defendants)

540. The City incorporates the allegations within all prior paragraphs within this Complaint as if they were fully set forth herein.

541. Florida's Deceptive and Unfair Trade Practices Act ("DUTPA") provides:

> Unfair methods of competition, unconscionable acts or practices, and unfair or deceptive acts or practices in the conduct of any trade or commerce are hereby declared unlawful. Fla. Stat. Ann. § 501.204(1).

542. Defendants have violated Florida's DUTPA because they engaged in unfair methods of competition, unconscionable acts or practices, and unfair or deceptive acts or practices in the conduct of commerce.

543. Sarasota is a "person" within the meaning of Fla. Stat. §501.203(6) and as envisioned in Fla. Stat. §501.211 (1).

544. Defendants engaged in "[t]rade or commerce" within the meaning of Fla. Stat. §501.203(8).

545. Defendants committed and continue to commit repeated and willful unfair or deceptive acts or practices, and unconscionable trade practices, in the conduct of commerce.

546. Specifically, Defendants engaged in unfair and/or deceptive trade practices by failing to report suspicious orders of opioids or suspicious prescribing and/or prevent the diversion of highly addictive prescription drugs to illegal sources.

547. Defendants failed to disclose the material facts that, *inter alia*, they were not in compliance with laws and regulations requiring that they maintain a system to prevent diversion,

and specifically monitor, investigate, report, and refuse suspicious orders and to maintain effective controls against diversion from their retail stores.

548. Defendants' unfair, deceptive, and unconscionable misrepresentations, concealments, and omissions were reasonably calculated to deceive the public, the healthcare community, and Florida communities, including the City.

549. Defendants acted knowingly, intentionally, and unlawfully.

550. Defendants' representations, concealments, and omissions constitute a willful course of conduct that continues to this day.

551. Defendants' unfair or deceptive acts or practices in violation of the FDUTPA offend Florida's public policy, are immoral, unethical, oppressive and unscrupulous, as well as malicious, wanton and manifesting of ill will, and they caused substantial injury to Sarasota.

552. Without Defendants' unfair and/or deceptive trade practices, opioid use, misuse, abuse, and addiction would not have become so widespread, and the opioid epidemic that now exists would have been averted. Defendants' actions were immoral, unethical, and unscrupulous and unlawfully caused the opioid epidemic in Florida and the City.

553. Defendants' sales, and distribution practices unlawfully caused an opioid and heroin plague and epidemic in the City. Each Defendant had a nondelegable duty to guard against and prevent the diversion of prescription opioids to other than legitimate channels.

554. The damages that the City seeks to recover were sustained as a direct and proximate result of the Defendants' intentional and unlawful acts and omissions.

555. The City seeks injunctive relief and economic losses resulting from Defendants' deceptive trade practices. The City does not seek damages for physical personal injury or any physical damage to property caused by Defendants' actions.

556. Defendants' misconduct alleged in this case does not concern a discrete event or discrete emergency of the sort a political subdivision would reasonably expect to occur, and is not part of the normal and expected costs of a local government's existence. The City alleges wrongful acts which are neither discrete nor of the sort a local government can reasonably expect.

WHEREFOE, the City demands judgment in its favor against the Defendants for damages pursuant to Fla. Stat. Ann § 501.201, *et seq.* together with all the costs of this action, including prejudgment interest, post-judgment interest, costs and expenses, attorney fees, and such other relief as this Court deems just and equitable.

COUNT III
Negligence
(Against All Defendants)

557. The City incorporates the allegations within all prior paragraphs within this Complaint as if they were fully set forth herein.

558. Under Florida law, to establish actionable negligence, the City must show, in addition to the existence of a duty, a breach of that duty, and injury resulting proximately therefrom. All such elements exist here.

559. Defendants have a duty to exercise reasonable care in distributing and selling highly dangerous opioid drugs in the City.

560. Defendants have a duty to exercise reasonable care under the circumstances, in light of the risks. This includes a duty not to cause foreseeable harm to others. In addition, these Defendants, having engaged in conduct that created an unreasonable risk of harm to others, had, and still have, a duty to exercise reasonable care to prevent the threatened harm.

561. In addition, Defendants each had a duty under Florida law to maintain effective controls against diversion of prescription opioids, to report suspicious orders of opioids, not to fill

suspicious orders unless and until due diligence had eliminated the suspicion, not to ignore red flags raised by prescriptions, and to guard against diversion from their pharmacy stores.

562. Defendants also misleadingly portrayed themselves as cooperating with law enforcement and actively working to combat the opioid epidemic when, in reality, Defendants failed to satisfy even their minimum, legally-required obligations to report suspicious prescribers. Defendants voluntarily undertook duties, through their statements to the media, regulators, and the public at large, to take all reasonable precautions to prevent drug diversion.

563. Upon information and belief, each of the Defendants repeatedly and intentionally breached its duties. These breaches included:

a. Selling prescription opioids in the supply chain when they knew, or should have known, that there was a substantial likelihood the sale was for non-medical purposes and that opioids are an inherently dangerous product when used for non-medical purposes;

b. Using unsafe distribution practices;

c. Inviting criminal activity into the City by disregarding precautionary measures built into Florida's statutory and regulatory requirements related to controlled substances, to which they agreed to adhere in obtaining licenses or registrations from the Florida Board of Pharmacy and the DEA;

d. Failing to comply with the public safety laws described above;

e. Failing to acquire or utilize special knowledge or skills that relate to the dangerous activity of selling opioids in order to prevent or ameliorate such significant dangers;

f. Failing to review prescription orders for red flags;

g. Failing to report suspicious orders or refuse to fill them; and

h. Failing to provide effective controls and procedures to guard against theft and diversion of controlled substances.

564. Each Defendant breached its duty to exercise the degree of care, prudence, watchfulness, and vigilance commensurate with the dangers involved in selling dangerous controlled substances.

565. Defendants acted with actual malice in breaching their duties, i.e., they have acted with a conscious disregard for the rights and safety of other persons, and said actions have a great probability of causing substantial harm.

566. The foreseeable harm from a breach of these duties is the sale, use, abuse, and diversion of prescription opioids.

567. The foreseeable harm from a breach of these duties also includes abuse, addiction, morbidity and mortality in the City.

568. Reasonably prudent distributors and dispensers of prescription opioids would have anticipated that the scourge of opioid addiction would wreak havoc on communities and the significant costs which would be imposed upon the governmental entities associated with those communities. Indeed, it is a violation of Florida law for Defendants not to report suspicious orders and exercise due diligence not to ship such orders unless and until the suspicion has been removed. The closed system of opioid distribution whereby wholesale distributors are the gatekeepers between manufacturers and pharmacies, and wherein all links in the chain have a duty to prevent diversion, exists for the purpose of controlling dangerous substances such as opioids and preventing diversion and abuse to prevent precisely these types of harms.

569. Reasonably prudent distributors and dispensers would know that failing to report suspicious prescribing, particularly while assuring the public of their commitment to fighting the opioid epidemic, would exacerbate problems of diversion and non-medical use of prescription opioids.

570. The City seeks economic losses (direct, incidental, or consequential pecuniary losses) resulting from the negligence of Defendants. It does not seek damages which may have been suffered by individual residents of the City for wrongful death, physical personal injury, serious emotional distress, or any physical damage to property caused by the actions of any of the Defendants.

571. The City is not asserting a cause of action under the CSA or other controlled-substances laws cited above. Rather, it seeks to remedy harms caused to it by the breach of duty created by these statutes and under common law.

572. These Defendants' breach of the duties described in this Count directly and proximately resulted in the injuries and damages alleged by the City.

573. The misconduct alleged in this case is ongoing and persistent.

574. The misconduct alleged in this case does not concern a discrete event or discrete emergency of the sort a political subdivision would reasonably expect to occur, and is not part of the normal and expected costs of a local government's existence. The City alleges wrongful acts which are neither discrete nor of the sort a local government can reasonably expect.

575. The City has incurred expenditures for special programs over and above its ordinary municipal services.

WHEREFORE, the City seeks all legal and equitable relief as allowed by law, except as expressly disavowed herein, including *inter alia* injunctive relief, compensatory damages, and all damages allowed by law to be paid by Defendants, attorney fees and costs, and pre- and post-judgment interest and such other relief as this Court deems just and equitable.

COUNT IV
Gross Negligence
(Against All Defendants)

576. The City incorporates the allegations within all prior paragraphs within this Complaint as if they were fully set forth herein.

577. To establish gross negligence, the City must show that Defendants acted with the absence of even slight diligence or scant care, or that they acted with indifference, or were negligent in a very high degree. The City has met its burden here.

578. Defendants have a duty to exercise reasonable care in distributing and selling highly dangerous drug opioids in the City.

579. Defendants have a duty to exercise reasonable care under the circumstances, in light of the risks. This includes a duty not to cause foreseeable harm to others. In addition, these Defendants, having engaged in conduct that created an unreasonable risk of harm to others, had, and still have, a duty to exercise reasonable care to prevent the threatened harm.

580. Defendants also misleadingly portrayed themselves as cooperating with law enforcement and actively working to combat the opioid epidemic when, in reality, Defendants failed to satisfy even their minimum, legally-required obligations to report suspicious prescribers. Defendants voluntarily undertook duties, through their statements to the media, regulators, and the public at large, to take all reasonable precautions to prevent drug diversion.

581. Upon information and belief, each of the Defendants repeatedly and intentionally breached its duties. These breaches included:

a. Selling prescription opioids in the supply chain when they knew, or should have known, that there was a substantial likelihood the sale was for non-medical purposes and that opioids are an inherently dangerous product when used for non-medical purposes;

b. Using unsafe distribution practices;

c. Inviting criminal activity into the City by disregarding precautionary measures built into Florida's statutory and regulatory requirements related to controlled substances, to which they agreed to adhere in

obtaining licenses or registrations from the Florida Board of Pharmacy and the DEA;

d. Failing to comply with the public safety laws described above;

e. Failing to acquire or utilize special knowledge or skills that relate to the dangerous activity of selling opioids in order to prevent or ameliorate such significant dangers;

f. Failing to review prescription orders for red flags;

g. Failing to report suspicious orders or refuse to fill them; and

h. Failing to provide effective controls and procedures to guard against theft and diversion of controlled substances.

582. Each Defendant breached its duty to exercise the degree of care, prudence, watchfulness, and vigilance commensurate with the dangers involved in selling dangerous controlled substances.

583. Defendants acted with actual malice in breaching their duties, i.e., they have acted with a conscious disregard for the rights and safety of other persons, and said actions have a great probability of causing substantial harm.

584. In breaching these duties, each Defendant showed the absence of even slight diligence or scant care, or that they acted with indifference, or were negligent in a very high degree.

585. As is described throughout this Complaint, Defendants acted without even slight diligence or scant care, and with indifference, and were negligent in a very high degree, disregarding the rights and safety of other persons, and said actions have a great probability of causing substantial harm.

586. The foreseeable harm from a breach of these duties is the sale, use, abuse, and diversion of prescription opioids.

587. The foreseeable harm from a breach of these duties also includes abuse, addiction, morbidity and mortality in the City, and among its employees and their dependents.

588. Reasonably prudent distributors and dispensers of prescription opioids would have anticipated that the scourge of opioid addiction would wreak havoc on communities and the significant costs which would be imposed upon the governmental entities associated with those communities.

589. Reasonably prudent distributors and dispensers would know that failing to report suspicious prescribing, particularly while assuring the public of their commitment to fighting the opioid epidemic, would exacerbate problems of diversion and non-medical use of prescription opioids.

590. The City seeks economic losses (direct, incidental, or consequential pecuniary losses) and resulting from the gross negligence of Defendants. The City does not seek damages which may have been suffered by individual residents of the City for wrongful death, physical personal injury, serious emotional distress, or any physical damage to property caused by the actions of Defendants.

591. Defendants' conduct, as described in this Complaint, constitutes an intentional failure to perform a manifest duty in reckless disregard of the consequences as affecting the life or property of another, including the City, and also implies an indifferent and thoughtless disregard of the consequences without the exertion of any effort to avoid them. Defendants have acted wantonly and willfully by inflicting injury intentionally or, alternatively, they have been utterly indifferent to the rights of others, including the City, in that they acted as if such rights did not exist.

592. The City is not asserting a cause of action under the CSA or other controlled-substances laws cited above. Rather, it seeks to remedy harms caused to it by the breach of duty created by these statutes and under common law.

593. Defendants conduct as described in this Count demonstrates wanton and willful disregard and indifference for others, including the City.

594. These Defendants' breach of the duties described in this Count directly and proximately resulted in the injuries and damages alleged by the City.

595. The misconduct alleged in this case is ongoing and persistent.

596. The misconduct alleged in this case does not concern a discrete event or discrete emergency of the sort a political subdivision would reasonably expect to occur, and is not part of the normal and expected costs of a local government's existence. The City alleges wrongful acts which are neither discrete nor of the sort a local government can reasonably expect.

597. The City has incurred expenditures for special programs over and above its ordinary municipal services.

WHEREFORE, the City seeks all legal and equitable relief as allowed by law, except as expressly disavowed herein, including *inter alia* injunctive relief, compensatory damages, and all damages allowed by law to be paid by Defendants, attorney fees and costs, and pre- and post-judgment interest and such other relief as this Court deems just and equitable.

COUNT V
Unjust Enrichment
(Against All Defendants)

598. The City incorporates the allegations within all prior paragraphs within this Complaint as if they were fully set forth herein.

599. As an expected and intended result of their conscious wrongdoing as set forth in this Complaint, Defendants have profited and benefited from the increase in the distribution, sale, and purchase of opioids within the City.

600. The City has expended substantial amounts of money in an effort to remedy or mitigate the societal harms caused by Defendants' conduct.

601. These expenditures include the provision of healthcare services and treatment services to people who use opioids.

602. These expenditures have helped sustain Defendants' businesses.

603. The City has conferred a benefit upon Defendants by paying for Defendants' externalities: the cost of the harms caused by Defendants' improper distribution and dispensing practices.

604. The City has also conferred a benefit upon Defendants by paying for purchases by unauthorized users of prescription opioids from the Defendants' supply chain for non-medical purposes.

605. By distributing a large volume of opioids within the City and by acting in concert with third parties, Defendants have unjustly enriched themselves at the City's expense.

606. The City has paid for the cost of each Defendants' externalities and Defendants have benefited from those payments because they allowed them to continue providing customers with a high volume of opioid products. Because of their conscious failure to exercise due diligence in preventing diversion and to maintain effective controls against diversion, Defendants obtained enrichment they would not otherwise have obtained. The enrichment was without justification and Plaintiffs lack a remedy provided by law.

607. Defendants have been unjustly enriched at the expense of the City. It would be inequitable for Defendants to retain the profits and benefits they have reaped from the unlawful conduct alleged herein.

608. The misconduct alleged in this case is ongoing and persistent.

609. The misconduct alleged in this case does not concern a discrete event or discrete emergency of the sort a political subdivision would reasonably expect to occur, and is not part of

the normal and expected costs of a local government's existence. The City alleges wrongful acts which are neither discrete nor of the sort a local government can reasonably expect.

610. The City has incurred expenditures for special programs over and above its ordinary municipal services.

WHEREFORE, the City seeks all legal and equitable relief as allowed by law, including disgorgement of Defendants' unjust enrichment, benefits, and ill-gotten gains, plus interest, acquired as a result of the unlawful or wrongful conduct alleged herein pursuant to common law and such other relief as this Court deems just and equitable.

COUNT VI
Violation of RICO, 18 U.S.C. § 1961, *et seq.* – Opioid Supply Chain Enterprise
(Against Defendants Walgreens and Walmart (the "RICO Supply Chain Defendants"))

611. The City incorporates the allegations within all prior paragraphs within this Complaint as if they were fully set forth herein.

612. At all relevant times, the RICO Supply Chain Defendants were and are "persons" under 18 U.S.C. § 1961(3) because they are entities capable of holding, and do hold, "a legal or beneficial interest in property."

613. The RICO Supply Chain Defendants together formed an association-in-fact enterprise, the Opioid Supply Chain Enterprise, for the purpose of increasing the quota for and profiting from the increased volume of opioid sales in the United States. The Opioid Supply Chain Enterprise is an association-in-fact enterprise within the meaning of § 1961. The Opioid Supply Chain Enterprise includes the RICO Supply Chain Defendants and the third parties described in Section I.K above.

614. The RICO Supply Chain Defendants were members of the NACDS. They used the NACDS and the collaborative efforts described in this Complaint to assist them in engaging in the pattern of racketeering activity that gives rise to the Count.

615. At all relevant times, the Opioid Supply Chain Enterprise: (a) had an existence separate and distinct from each of the RICO Supply Chain Defendants; (b) was separate and distinct from the pattern of racketeering in which the RICO Supply Chain Defendants engaged; (c) was an ongoing and continuing organization consisting of legal entities, including each of the RICO Supply Chain Defendants; (d) was characterized by interpersonal relationships among the RICO Supply Chain Defendants; (e) had sufficient longevity for the enterprise to pursue its purpose; and (f) functioned as a continuing unit. Each member of the Opioid Supply Chain Enterprise participated in the conduct of the enterprise, including patterns of racketeering activity, and shared in the astounding growth of profits supplied by fraudulently inflating opioid sales.

616. The RICO Supply Chain Defendants carried out, or attempted to carry out, a scheme to defraud federal and state regulators, and the American public by knowingly conducting or participating in the conduct of the Opioid Supply Chain Enterprise through a pattern of racketeering activity within the meaning of 18 U.S.C. § 1961(1) that employed the use of mail and wire facilities, in violation of 18 U.S.C. § 1341 (mail fraud) and § 1343 (wire fraud).

617. The RICO Supply Chain Defendants committed, conspired to commit, and/or aided and abetted in the commission of at least two predicate acts of racketeering activity (i.e. violations of 18 U.S.C. §§ 1341 and 1343) within the past ten years. The multiple acts of racketeering activity that the RICO Supply Chain Defendants committed, or aided and abetted in the commission of, were related to each other, posed a threat of continued racketeering activity, and therefore constitute a "pattern of racketeering activity." The racketeering activity was made possible by the

RICO Supply Chain Defendants' regular use of the facilities, services, distribution channels, and employees of the Opioid Supply Chain Enterprise. The RICO Supply Chain Defendants participated in the scheme to defraud by using mail, telephone and the Internet to transmit mailings and wires in interstate or foreign commerce.

618. The RICO Supply Chain Defendants also conducted and participated in the conduct of the affairs of the Opioid Supply Chain Enterprise through a pattern of racketeering activity by the felonious buying, selling, or otherwise dealing in a controlled substance or listed chemical (as defined in section 102 of the Controlled Substance Act), punishable under any law of the United States.

619. The RICO Supply Chain Defendants committed crimes that are punishable as felonies under the laws of the United States. Specifically, 21 U.S.C. § 843(a)(4) makes it unlawful for any person to knowingly or intentionally furnish false or fraudulent information in, or omit any material information from, any application, report, record or other document required to be made, kept or filed under this subchapter. A violation of § 843(a)(4) is punishable by up to four years in jail, making it a felony. 21 U.S.C. § 843(d)(1).

620. Each of the RICO Supply Chain Defendants is a registrant as defined in the CSA. Their status as registrants under the CSA requires that they maintain effective controls against diversion of controlled substances in schedule I or II, design and operate a system to disclose to the registrant suspicious orders of controlled substances and inform the DEA of suspicious orders when discovered by the registrant. 21 U.S.C. § 823; 21 C.F.R. § 1301.74(b).

621. The RICO Supply Chain Defendants' predicate acts of racketeering (18 U.S.C. § 1961(1)) include, but are not limited to:

a. Mail Fraud: The RICO Supply Chain Defendants violated 18 U.S.C. § 1341 by sending or receiving, or by causing to be sent and/or received, materials via U.S. mail

or commercial interstate carriers for the purpose of executing the unlawful scheme to design, manufacture, market, and sell the prescription opioids by means of false pretenses, misrepresentations, promises, and omissions.

b. Wire Fraud: The RICO Supply Chain Defendants violated 18 U.S.C. § 1343 by transmitting and/or receiving, or by causing to be transmitted and/or received, materials by wire for the purpose of executing the unlawful scheme to design, manufacture, market, and sell the prescription opioids by means of false pretenses, misrepresentations, promises, and omissions.

c. Controlled Substance Violations: The RICO Supply Chain Defendants violated 21 U.S.C. § 843 by knowingly or intentionally furnishing false or fraudulent information in, and/or omitting material information from, documents filed with the DEA.

622. The RICO Supply Chain Defendants conducted their pattern of racketeering activity in this jurisdiction and throughout the United States through this enterprise.

623. The RICO Supply Chain Defendants aided and abetted others in the violations of the above laws, thereby rendering them indictable as principals in the 18 U.S.C. §§ 1341 and 1343 offenses.

624. The RICO Supply Chain Defendants hid from the general public and suppressed and/or ignored warnings from third parties, whistleblowers and governmental entities about the reality of the suspicious orders that the RICO Supply Chain Defendants and members of the Enterprise were filling on a daily basis – leading to the diversion of hundreds of millions of doses of prescriptions opioids into the illicit market.

625. The RICO Supply Chain Defendants, with knowledge and intent, agreed to the overall objective of their fraudulent scheme and participated in the common course of conduct to commit acts of fraud and indecency in distributing and selling prescription opioids.

626. Indeed, for the Defendants' fraudulent scheme to work, each of the Defendants had to agree to implement similar tactics regarding distributing prescription opioids and refusing to report suspicious orders.

627. As described herein, the RICO Supply Chain Defendants engaged in a pattern of related and continuous predicate acts for years. The predicate acts constituted a variety of unlawful activities, each conducted with the common purpose of obtaining significant monies and revenues from the sale of their highly addictive and dangerous drugs. The predicate acts also had the same or similar results, participants, victims, and methods of commission. The predicate acts were related and not isolated events.

628. The predicate acts all had the purpose of creating the opioid epidemic that substantially injured Plaintiff's business and property, while simultaneously generating billion-dollar revenue and profits for the RICO Supply Chain Defendants. The predicate acts were committed or caused to be committed by the RICO Supply Chain Defendants through their participation in the Opioid Supply Chain Enterprise and in furtherance of its fraudulent scheme.

629. The pattern of racketeering activity alleged herein and the Opioid Supply Chain Enterprise are separate and distinct from each other. Likewise, the RICO Supply Chain Defendants are distinct from the enterprise.

630. The pattern of racketeering activity alleged herein is continuing as of the date of this Complaint and, upon information and belief, will continue into the future unless enjoined by this Court.

631. Many of the precise dates of the RICO Supply Chain Defendants' criminal actions at issue here have been hidden by Defendants and cannot be alleged without access to Defendants' books and records. Indeed, an essential part of the successful operation of the Opioid Supply Chain Enterprise alleged herein depended upon secrecy.

632. By intentionally refusing to report and halt suspicious orders of their prescription opioids, Defendants engaged in a fraudulent scheme and unlawful course of conduct constituting a pattern of racketeering activity.

633. It was foreseeable to the RICO Supply Chain Defendants that the City would be harmed when they refused to report and halt suspicious orders, because their violation of the duties imposed by the CSA and Code of Federal Regulations allowed the widespread diversion of prescription opioids out of appropriate medical channels and into the illicit drug market – causing the opioid epidemic that the CSA intended to prevent.

634. The last racketeering incident occurred within five years of the commission of a prior incident of racketeering.

635. The RICO Supply Chain Defendants' violations of law and their pattern of racketeering activity directly and proximately caused the City injury in its business and property. The RICO Supply Chain Defendants' pattern of racketeering activity, including their refusal to identify, report and halt suspicious orders of controlled substances, logically, substantially and foreseeably cause an opioid epidemic. The City was injured by the RICO Supply Chain Defendants' pattern of racketeering activity and the opioid epidemic that they created.

636. The RICO Supply Chain Defendants knew that the opioids they supplied were unsuited to treatment of long-term, chronic, non-acute, and non-cancer pain, or for any other use not approved by the FDA, and knew that opioids were highly addictive and subject to abuse. Nevertheless, the RICO Supply Chain Defendants engaged in a scheme of deception, that utilized the mail and wires as part of their fraud, in order to increase sales of their opioid products by refusing to identify, report suspicious orders of prescription opioids that they knew were highly addictive, subject to abuse, and were actually being diverted into the illegal market.

637. The RICO Supply Chain Defendants' predicate acts and pattern of racketeering activity were a cause of the opioid epidemic which has injured the City in the form of substantial losses of money and property that logically, directly and foreseeably arise from the opioid-addiction epidemic.

638. Specifically, the City's injuries, as alleged throughout this complaint, and expressly incorporated herein by reference, include millions of dollars in increased law enforcement and public works expenditures, increased expenditures for overtime, the hiring of additional City employees, mental health treatment and workers' compensation for its employees, increased emergency and treatment services, damage to emergency equipment and vehicles, and lost productivity, economic opportunity, and tax revenue.

639. The City's injuries were proximately caused by Defendants' racketeering activities because they were the logical, substantial and foreseeable cause of the City's injuries. But for the opioid-addiction epidemic created by Defendants' conduct, the City would not have lost money or property.

640. The City's injuries were directly caused by the RICO Supply Chain Defendants' pattern of racketeering activities.

641. The City is most directly harmed and there are no other plaintiffs better suited to seek a remedy for the economic harms at issue here.

WHEREFORE, the City seeks all legal and equitable relief as allowed by law, including, *inter alia*, actual damages; treble damages; equitable and/or injunctive relief in the form of court-supervised corrective communication, actions and programs; forfeiture as deemed proper by the Court; attorney's fees; all costs and expenses of suit; and pre- and post-judgment interest, and any other relief the Court deems just and applicable.

PRAYER FOR RELIEF

WHEREFORE, the City of Sarasota, Florida requests the following relief:

A finding that by the acts alleged herein, Defendants violated the Florida Deceptive and Unfair Trade Practices Act, Fla. Stat. Ann. § 501.204, *et seq.*;

A finding that, by the acts alleged herein, the RICO Supply Chain Defendants violated 18 U.S.C. § 1961, *et. seq.*

Actual damages, treble damages, and equitable relief under 18. U.S.C. § 1964 for violations of 18 U.S.C. § 1961, *et. seq.*

A finding that by the acts alleged herein, Defendants have created a public nuisance;

An injunction permanently enjoining Defendants from engaging the acts and practices that caused the public nuisance;

An order directing Defendants to abate and pay damages for the public nuisance;

A finding that Defendants were negligent;

A finding that Defendants were grossly negligent;

A finding that Defendants were unjustly enriched;

Compensatory damages in an amount sufficient to fairly and completely compensate for all damages alleged herein;

Restitution or disgorgement of Defendants' unjust enrichment, benefits, and ill-gotten gains, plus interest, acquired as a result of the unlawful or wrongful conduct alleged herein pursuant to common law;

Costs, filing fees, pre and post judgment interest, and attorney's fees; and

For all other and further relief to which this Court finds it is entitled.

JURY DEMAND

Plaintiff demands trial by jury as to all issues and claims so triable.

Dated: May 6, 2022

/s/ *William F. Robertson*

William F. Robertson, Jr. (FBN: 436607)
Robertson Law Firm P.A.
1990 9th Street, Suite 100
Sarasota, Florida 34236
Tel: (941) 919-3959
Bill@Robertson.law

MOTLEY RICE, LLC

Linda Singer
Motley Rice LLC
401 9th Street NW
Suite 1001
Washington, DC 20004
(202) 386-9626
lsinger@motleyrice.com
esmith@motleyrice.com

Joseph Rice
Lisa Saltzburg
Motley Rice LLC
28 Bridgeside Blvd.
Mount Pleasant, South Carolina 29464
(843) 216-9000
jrice@motleyrice.com
lsaltzburg@motleyrice.com

Counsel for Plaintiff